

**Dossier zur Nutzenbewertung  
gemäß § 35a SGB V**

*Lonapegsomatropin (Skytrofa®)*

Ascendis Pharma Endocrinology GmbH

**Separater Anhang 4-I**

*Wachstumsstörungen bei Kindern und Jugendlichen von  
3 bis 18 Jahren aufgrund unzureichender Sekretion des  
endogenen Wachstumshormons*

Medizinischer Nutzen und  
medizinischer Zusatznutzen,  
Patientengruppen mit therapeutisch  
bedeutsamem Zusatznutzen

## Inhaltsverzeichnis

Table 1.8 Annualized Height Velocity at Week 52: ANCOVA Analysis, Missing Data Imputed with Multiple Imputation, subgroup analysis.....	3
Table 1.6.m Change from Baseline in Height SDS at Week 52 ANCOVA Analysis, subgroup analysis.....	7
Table 1.12.m Summary of Adverse Events, subgroup analysis by age.....	11
Table 1.13.m Summary of Adverse Events, subgroup analysis by gender.....	17
Table 1.14.m Summary of Adverse Events, subgroup analysis by baseline GH-stimulation strata.....	23
Table 1.15.m Summary of Adverse Events, subgroup analysis by etiology and extend of GHD.....	29
Table 1.16.m Summary of Adverse Events, subgroup analysis by peak stimulated GH concentration at baseline.....	38
Table 1.24.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE $\geq$ 10% in any treatment group .....	44
Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE $\geq$ 10% in any treatment group.....	60
Table 1.26.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata, AE $\geq$ 10% in any treatment group.....	100
Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE $\geq$ 10% in any treatment group.....	118
Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE $\geq$ 10% in any treatment group.....	185
Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age.....	205
Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender.....	870
Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata.....	1534
Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD.....	2199
Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration.....	3187
Table 1.30.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age.....	3808
Table 1.31.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender.....	3816
Table 1.32.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by baseline GH-stimulation strata.....	3824
Table 1.33.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD.....	3832
Table 1.34.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by peak stimulated GH concentration.....	3843

Table 1.39.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age.....	3849
Table 1.40.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender.....	3859
Table 1.41.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by baseline GH-stimulation strata.....	3867
Table 1.42.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD.....	3875
Table 1.43.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by peak stimulated GH concentration.....	3887

Table 1.8.m Annualized Height Velocity at Week 52: ANCOVA Analysis, Missing Data Imputed with Multiple Imputation, subgroup analysis

Subgroup Treatment	Baseline	Week 52	Week 52	Lonapegsomatropin vs. Daily somatropin			
	Mean (95% CI)	Mean (95% CI)	LS-Mean (95% CI)	Difference of LS-Mean (95% CI)	Hedge's g (95% CI)	Interaction p-value	Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )
Age							
AGE < 6 Years							
Lonapeg somatropin	4.91 (3.95, 5.87)	11.51 (11.05, 11.96)	11.76 (11.12, 12.39)	1.359 (0.620, 2.098)	0.688 (0.272, 1.105)	0.302	P=0.695, I <sup>2</sup> =0%
Daily somatropin	4.46 (3.68, 5.24)	10.21 (9.61, 10.82)	10.29 (9.55, 11.04)				
AGE ≥ 6 Years							
Lonapeg somatropin	3.59 (3.17, 4.01)	10.34 (10.00, 10.69)	10.45 (10.09, 10.81)	0.620 (0.113, 1.127)	0.289 (0.003, 0.574)		P=0.685, I <sup>2</sup> =0%
Daily somatropin	3.76 (3.24, 4.28)	9.68 (9.18, 10.17)	9.83 (9.38, 10.28)				
Gender							
Male							
Lonapeg somatropin	4.04 (3.58, 4.50)	10.65 (10.35, 10.95)	10.67 (10.40, 10.93)	0.935 (0.482, 1.388)	0.417 (0.160, 0.674)	0.313	P=0.656, I <sup>2</sup> =0%

Table 1.8.m Annualized Height Velocity at Week 52: ANCOVA Analysis, Missing Data Imputed with Multiple Imputation, subgroup analysis

				Lonapegsomatropin vs. Daily somatropin			
	Baseline	Week 52	Week 52				
Subgroup Treatment	Mean (95% CI)	Mean (95% CI)	LS-Mean (95% CI)	Difference of LS-Mean (95% CI)	Hedge's g (95% CI)	Interaction p-value	Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )
Gender							
Male							
Daily somatropin	4.10 (3.65, 4.55)	9.77 (9.34, 10.19)	9.73 (9.37, 10.10)				
Female							
Lonapeg somatropin	3.42 (2.55, 4.29)	11.23 (10.41, 12.06)	11.08 (10.44, 11.73)	0.297 (-0.896, 1.491)	0.318 (-0.263, 0.900)		P=0.622, I <sup>2</sup> =0%
Daily somatropin	3.17 (1.85, 4.49)	10.36 (9.40, 11.32)	10.75 (9.88, 11.63)				
Baseline GH-stimulation strata							
≤ 5 ng/mL							
Lonapeg somatropin	3.80 (3.15, 4.45)	11.68 (11.05, 12.30)	11.92 (11.29, 12.54)	0.900 (-0.024, 1.823)	0.440 (0.015, 0.864)	0.878	P=0.742, I <sup>2</sup> =0%
Daily somatropin	4.01 (3.43, 4.59)	10.47 (9.72, 11.21)	11.02 (10.19, 11.84)				
>5 ng/mL							
Lonapeg somatropin	4.00 (3.47, 4.53)	10.35 (10.07, 10.64)	10.35 (9.99, 10.70)	0.794 (0.345, 1.243)	0.413 (0.131, 0.695)		P=0.863, I <sup>2</sup> =0%

Table 1.8.m Annualized Height Velocity at Week 52: ANCOVA Analysis, Missing Data Imputed with Multiple Imputation, subgroup analysis

Subgroup Treatment	Baseline			Lonapegsomatropin vs. Daily somatropin			
	Mean (95% CI)	Week 52 Mean (95% CI)	Week 52 LS-Mean (95% CI)	Difference of LS-Mean (95% CI)	Hedge's g (95% CI)	Interaction p-value	Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )
Baseline GH-stimulation strata							
>5 ng/mL							
Daily somatropin	3.88 (3.26, 4.50)	9.62 (9.19, 10.05)	9.54 (9.12, 9.97)				
Etiology and extend of GHD							
Isolated Idiopathic							
Lonapeg somatropin	4.10 (3.54, 4.66)	10.41 (10.11, 10.71)	10.43 (10.07, 10.79)	0.789 (0.333, 1.246)	0.404 (0.135, 0.673)	0.451	P=0.674, I <sup>2</sup> =0%
Daily somatropin	4.12 (3.59, 4.65)	9.64 (9.21, 10.07)	9.64 (9.21, 10.08)				
Isolated Organic							
Lonapeg somatropin	4.43 (3.66, 5.20)	11.40 (10.71, 12.09)	11.50 (10.84, 12.16)	1.560 (0.482, 2.638)	0.480 (-0.159, 1.118)		P=0.322, I <sup>2</sup> =0%
Daily somatropin	3.23 (1.98, 4.48)	9.88 (9.17, 10.59)	9.99 (9.18, 10.81)				
Multiple Pituitary Hormone Deficiencies							
Lonapeg somatropin	2.83 (2.18, 3.48)	11.40 (11.25, 11.55)	12.68 (11.33, 14.03)	0.480 (-2.045, 3.005)	0.320 (-0.458, 1.098)		P=1.000, I <sup>2</sup> =0%

Table 1.8.m Annualized Height Velocity at Week 52: ANCOVA Analysis, Missing Data Imputed with Multiple Imputation, subgroup analysis

				Lonapegsomatropin vs. Daily somatropin			
	Baseline	Week 52	Week 52				
Subgroup Treatment	Mean (95% CI)	Mean (95% CI)	LS-Mean (95% CI)	Difference of LS-Mean (95% CI)	Hedge's g (95% CI)	Interaction p-value	Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )
Etiology and extend of GHD							
Multiple Pituitary Hormone Deficiencies							
Daily somatropin	3.86 (2.84, 4.88)	11.50 (9.73, 13.27)	12.20 (10.17, 14.23)				
Peak stimulated GH concentration at baseline							
< 8 ng/mL							
Lonapeg somatropin	3.81 (3.30, 4.32)	10.91 (10.54, 11.27)	11.02 (10.64, 11.39)	0.839 (0.318, 1.359)	0.412 (0.136, 0.688)	0.834	P=0.515, I <sup>2</sup> =0%
Daily somatropin	3.81 (3.32, 4.30)	9.96 (9.50, 10.42)	10.17 (9.68, 10.66)				
≥ 8 ng/mL							
Lonapeg somatropin	4.26 (3.59, 4.93)	10.33 (9.93, 10.72)	10.69 (10.11, 11.27)	1.003 (0.264, 1.743)	0.378 (-0.068, 0.824)		P=0.072, I <sup>2</sup> =69%
Daily somatropin	4.25 (3.25, 5.25)	9.64 (8.92, 10.37)	9.66 (9.06, 10.26)				
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. Heterogeneity Test was tested on Difference of LS-Mean.							

Table 1.6.m Change from Baseline in Height SDS at Week 52 ANCOVA Analysis, subgroup analysis

Subgroup Treatment	Baseline	Week 52	Week 52	Lonapegsomatropin vs. Daily somatropin			
	Mean (95% CI)	Mean (95% CI)	LS-Mean (95% CI)	Difference of LS-Mean (95% CI)	Hedge's g (95% CI)	Interaction p-value	Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )
Age							
AGE < 6 Years							
Lonapeg somatropin	-2.71 (-2.87, -2.56)	1.24 (1.14, 1.34)	1.31 (1.18, 1.44)	0.292 (0.137, 0.447)	0.684 (0.267, 1.100)	0.226	P=0.714, I <sup>2</sup> =0%
Daily somatropin	-2.58 (-2.76, -2.40)	0.97 (0.85, 1.09)	1.00 (0.85, 1.16)				
AGE ≥ 6 Years							
Lonapeg somatropin	-2.72 (-2.84, -2.60)	0.88 (0.81, 0.96)	0.92 (0.86, 0.98)	0.084 (-0.005, 0.173)	0.233 (-0.055, 0.522)		P=0.742, I <sup>2</sup> =0%
Daily somatropin	-2.90 (-3.09, -2.72)	0.77 (0.68, 0.87)	0.84 (0.76, 0.92)				
Gender							
Male							
Lonapeg somatropin	-2.71 (-2.81, -2.61)	0.99 (0.92, 1.06)	1.00 (0.95, 1.05)	0.190 (0.101, 0.280)	0.388 (0.129, 0.647)	0.075	P=0.662, I <sup>2</sup> =0%



Table 1.6.m Change from Baseline in Height SDS at Week 52 ANCOVA Analysis, subgroup analysis

				Lonapegsomatropin vs. Daily somatropin			
	Baseline	Week 52	Week 52				
Subgroup Treatment	Mean (95% CI)	Mean (95% CI)	LS-Mean (95% CI)	Difference of LS-Mean (95% CI)	Hedge's g (95% CI)	Interaction p-value	Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )
Gender							
Male							
Daily somatropin	-2.74 (-2.88, -2.59)	0.82 (0.73, 0.90)	0.80 (0.73, 0.88)				
Female							
Lonapeg somatropin	-2.76 (-2.98, -2.54)	1.05 (0.89, 1.21)	1.05 (0.96, 1.15)	-0.083 (-0.266, 0.099)	0.208 (-0.372, 0.788)		P=0.479, I <sup>2</sup> =0%
Daily somatropin	-3.00 (-3.36, -2.63)	0.94 (0.77, 1.10)	1.13 (0.99, 1.26)				
Baseline GH-stimulation strata							
≤ 5 ng/mL							
Lonapeg somatropin	-3.02 (-3.25, -2.79)	1.16 (1.02, 1.29)	1.23 (1.11, 1.34)	0.222 (0.048, 0.396)	0.367 (-0.060, 0.795)	0.5	P=0.502, I <sup>2</sup> =0%
Daily somatropin	-3.26 (-3.62, -2.90)	0.95 (0.79, 1.11)	1.01 (0.86, 1.17)				
>5 ng/mL							
Lonapeg somatropin	-2.58 (-2.66, -2.50)	0.94 (0.87, 1.01)	0.97 (0.90, 1.04)	0.137 (0.049, 0.226)	0.359 (0.075, 0.642)		P=0.580, I <sup>2</sup> =0%
Daily somatropin	-2.63 (-2.74, -2.52)	0.81 (0.73, 0.89)	0.83 (0.75, 0.91)				

Table 1.6.m Change from Baseline in Height SDS at Week 52 ANCOVA Analysis, subgroup analysis

Subgroup Treatment	Baseline	Week 52	Week 52	Lonapegsomatropin vs. Daily somatropin			
	Mean (95% CI)	Mean (95% CI)	LS-Mean (95% CI)	Difference of LS-Mean (95% CI)	Hedge's g (95% CI)	Interaction p-value	Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )
Etiology and extend of GHD							
Isolated Idiopathic							
Lonapeg somatropin	-2.65 (-2.74, -2.55)	0.94 (0.88, 1.01)	0.96 (0.89, 1.03)	0.152 (0.066, 0.238)	0.415 (0.143, 0.688)	0.535	P=0.362, I <sup>2</sup> =0%
Daily somatropin	-2.64 (-2.77, -2.51)	0.78 (0.70, 0.86)	0.81 (0.73, 0.89)				
Isolated Organic							
Lonapeg somatropin	-2.78 (-3.00, -2.56)	1.11 (0.97, 1.24)	1.19 (1.05, 1.33)	0.261 (0.016, 0.505)	0.309 (-0.334, 0.951)		P=0.100, I <sup>2</sup> =63%
Daily somatropin	-3.38 (-3.85, -2.91)	0.99 (0.79, 1.19)	0.94 (0.76, 1.11)				
Multiple Pituitary Hormone Deficiencies							
Lonapeg somatropin	-3.46 (-3.99, -2.93)	1.17 (0.93, 1.42)	1.45 (1.22, 1.68)	0.170 (-0.262, 0.602)	0.290 (-0.487, 1.067)		P=1.000, I <sup>2</sup> =0%
Daily somatropin	-3.43 (-4.02, -2.84)	1.20 (0.88, 1.52)	1.28 (0.93, 1.63)				

Table 1.6.m Change from Baseline in Height SDS at Week 52 ANCOVA Analysis, subgroup analysis

Subgroup Treatment	Baseline		Week 52		Lonapegsomatropin vs. Daily somatropin		
	Mean (95% CI)	Mean (95% CI)	LS-Mean (95% CI)	Difference of LS-Mean (95% CI)	Hedge's g (95% CI)	Interaction p-value	Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )
Peak stimulated GH concentration at baseline							
< 8 ng/mL							
Lonapeg somatropin	-2.78 (-2.90, -2.67)	1.05 (0.97, 1.12)	1.09 (1.02, 1.16)	0.180 (0.079, 0.281)	0.396 (0.116, 0.675)	0.939	P=1.000, I <sup>2</sup> =0%
Daily somatropin	-2.86 (-3.04, -2.68)	0.86 (0.76, 0.95)	0.91 (0.82, 1.00)				
≥ 8 ng/mL							
Lonapeg somatropin	-2.56 (-2.70, -2.42)	0.91 (0.80, 1.01)	1.00 (0.89, 1.11)	0.162 (0.023, 0.301)	0.222 (-0.221, 0.666)		P=0.050, I <sup>2</sup> =74%
Daily somatropin	-2.62 (-2.77, -2.46)	0.84 (0.73, 0.96)	0.84 (0.73, 0.95)				
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. Heterogeneity Test was tested on Difference of LS-Mean.							

Table 1.12.m Summary of Adverse Events, subgroup analysis by age

		Lonapegsomatropin vs. Daily somatropin									
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )				
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years											
Treatment emergent adverse events (TEAE)	91.0% (81.5, 95.9)	86.1% (70.7, 94.1)	P=0.015, I <sup>2</sup> =76.5%	P=0.042, I <sup>2</sup> =69%	1.672 (0.439, 6.365)	1.054 (0.913, 1.216) 0.477	0.046 (-0.079 - 0.172)	P=0.903, I <sup>2</sup> =0%	P=0.517, I <sup>2</sup> =0%	P=0.576, I <sup>2</sup> =0%	P=0.681
TEAEs related to study drug	32.8% (22.7, 44.9)	13.9% (5.9, 29.3)	P=0.000, I <sup>2</sup> =88.7%	P=0.331, I <sup>2</sup> =0%							
Serious AEs	3.0% (0.7, 11.2)	5.6% (1.4, 19.7)	P=0.168, I <sup>2</sup> =0%	P=0.153, I <sup>2</sup> =0%	0.500 (0.066, 3.815)	0.524 (0.079, 3.470) 0.503	-0.027 (-0.111 - 0.058)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.588

Table 1.12.m Summary of Adverse Events, subgroup analysis by age

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years											
Serious AEs related to study drug	1.5% (0.2, 9.8)	0.0% (0.0, 100.0)	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
TEAEs leading to any action on study drug	10.4% (5.1, 20.3)	16.7% (7.7, 32.5)	P=0.155, I <sup>2</sup> =35.7%	P=0.010, I <sup>2</sup> =0%							
TEAEs leading to discontinuation of study drug	1.5% (0.2, 9.8)	0.0% (0.0, 100.0)	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.990

Table 1.12.m Summary of Adverse Events, subgroup analysis by age

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years											
TEAEs leading to death	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.12.m Summary of Adverse Events, subgroup analysis by age

				Lonapegsomatropin vs. Daily somatropin							
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )				
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years											
Treatment emergent adverse events (TEAE)	85.5% (78.6, 90.5)	79.5% (68.7, 87.2)	P=0.000, I <sup>2</sup> =86.9%	P=0.007, I <sup>2</sup> =82%	1.607 (0.736, 3.508)	1.078 (0.947, 1.227) 0.259	0.062 (-0.043 - 0.166)	P=0.445, I <sup>2</sup> =0%	P=0.587, I <sup>2</sup> =0%	P=0.745, I <sup>2</sup> =0%	
TEAEs related to study drug	27.5% (20.7, 35.6)	32.9% (23.1, 44.4)	P=0.000, I <sup>2</sup> =93.9%	P=0.015, I <sup>2</sup> =82%							
Serious AEs	2.2% (0.7, 6.5)	1.4% (0.2, 9.1)	P=0.385, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	1.595 (0.165, 15.430)	1.587 (0.168, 15.018) 0.687	0.008 (-0.028 - 0.044)	P=0.388, I <sup>2</sup> =0%	P=0.388, I <sup>2</sup> =0%	P=0.363, I <sup>2</sup> =0%	

Table 1.12.m Summary of Adverse Events, subgroup analysis by age

					Lonapegsomatropin vs. Daily somatropin						
% of Subjects with	Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			Interaction
	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	
Age ≥ 6 years											
Serious AEs related to study drug	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
TEAEs leading to any action on study drug	10.1% (6.1, 16.4)	13.7% (7.5, 23.6)	P=0.000, I <sup>2</sup> =88.6%	P=0.001, I <sup>2</sup> =85%							
TEAEs leading to discontinuation of study drug	0.7% (0.1, 5.0)	0.0% (0.0, 100.0)	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.12.m Summary of Adverse Events, subgroup analysis by age

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years											
TEAEs leading to death	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.											

Table 1.13.m Summary of Adverse Events, subgroup analysis by gender

				Lonapegsomatropin vs. Daily somatropin							
% of Subjects with	Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			Interaction
	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	
Male											
Treatment emergent adverse events (TEAE)	87.9% (82.1, 92.0)	83.5% (74.4, 89.8)	P=0.000, I <sup>2</sup> =0%	P=0.001, I <sup>2</sup> =86%	1.470 (0.681, 3.173)	1.050 (0.949, 1.161) 0.346	0.041 (-0.044 - 0.127)	P=0.189, I <sup>2</sup> =4202%	P=0.952, I <sup>2</sup> =0%	P=0.830, I <sup>2</sup> =0%	P=0.868
TEAEs related to study drug	32.4% (25.8, 39.7)	26.4% (18.3, 36.3)	P=0.000, I <sup>2</sup> =95.8%	P=0.135, I <sup>2</sup> =54%							
Serious AEs	2.9% (1.2, 6.8)	3.3% (1.1, 9.7)	P=0.163, I <sup>2</sup> =35.9%	P=0.541, I <sup>2</sup> =0%	0.865 (0.201, 3.724)	0.869 (0.213, 3.544) 0.845	-0.004 (-0.049 - 0.040)	P=0.689, I <sup>2</sup> =0%	P=0.687, I <sup>2</sup> =0%	P=0.777, I <sup>2</sup> =0%	P=0.809

Table 1.13.m Summary of Adverse Events, subgroup analysis by gender

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male											
Serious AEs related to study drug	0.6% (0.1, 4.0)	0.0% (0.0, 100.0)	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
TEAEs leading to any action on study drug	11.0% (7.1, 16.6)	14.3% (8.5, 23.1)	P=0.000, I <sup>2</sup> =89.2%	P=0.000, I <sup>2</sup> =85%							
TEAEs leading to discontinu ation of study drug	1.2% (0.3, 4.5)	0.0% (0.0, 100.0)	P=0.096, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.011 (-0.004 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.629

Table 1.13.m Summary of Adverse Events, subgroup analysis by gender

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male											
TEAEs leading to death	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.13.m Summary of Adverse Events, subgroup analysis by gender

				Lonapegsomatropin vs. Daily somatropin							
% of Subjects with	Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			Interaction
	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	
Female											
Treatment emergent adverse events (TEAE)	84.4% (67.5, 93.3)	72.2% (48.1, 87.9)	P=0.975, I <sup>2</sup> =0%	P=0.182, I <sup>2</sup> =34%	2.121 (0.523, 8.609)	1.175 (0.847, 1.630) 0.335	0.125 (-0.117 - 0.368)	P=0.344, I <sup>2</sup> =0%	P=0.206, I <sup>2</sup> =3757%	P=0.229, I <sup>2</sup> =3076%	
TEAEs related to study drug	12.5% (4.8, 28.9)	27.8% (12.1, 51.9)	P=0.005, I <sup>2</sup> =0%	P=0.055, I <sup>2</sup> =67%							
Serious AEs	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.13.m Summary of Adverse Events, subgroup analysis by gender

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female											
Serious AEs related to study drug	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
TEAEs leading to any action on study drug	6.3% (1.6, 21.8)	16.7% (5.5, 40.9)	P=0.051, I <sup>2</sup> =0%	P=0.018, I <sup>2</sup> =0%							
TEAEs leading to discontinu ation of study drug	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.13.m Summary of Adverse Events, subgroup analysis by gender

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female											
TEAEs leading to death	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.											

Table 1.14.m Summary of Adverse Events, subgroup analysis by baseline GH-stimulation strata

				Lonapegsomatropin vs. Daily somatropin							
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )				
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL											
Treatment emergent adverse events (TEAE)	91.9% (82.0, 96.6)	88.2% (72.5, 95.5)	P=0.020, I <sup>2</sup> =0%	P=0.041, I <sup>2</sup> =0%	1.506 (0.357, 6.358)	1.038 (0.904, 1.192) 0.594	0.034 (-0.090 - 0.157)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.636
TEAEs related to study drug	29.0% (19.1, 41.4)	38.2% (23.7, 55.3)	P=0.007, I <sup>2</sup> =85.3%	P=0.141, I <sup>2</sup> =53%							
Serious AEs	0.0% (0.0, 100.0)	5.9% (1.5, 20.7)	P=1.000, I <sup>2</sup> =0%	P=0.728, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.059 (-0.138 - 0.020)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.734, I <sup>2</sup> =0%	P=0.108



Table 1.14.m Summary of Adverse Events, subgroup analysis by baseline GH-stimulation strata

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
	Baseline GH-stimulation strata: ≤ 5 ng/mL										
Serious AEs related to study drug	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
TEAEs leading to any action on study drug	6.5% (2.4, 16.0)	20.6% (10.1, 37.3)	P=0.006, I <sup>2</sup> =0%	P=0.003, I <sup>2</sup> =83%							
TEAEs leading to discontinuation of study drug	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.604

Table 1.14.m Summary of Adverse Events, subgroup analysis by baseline GH-stimulation strata

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL											
TEAEs leading to death	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.14.m Summary of Adverse Events, subgroup analysis by baseline GH-stimulation strata

				Lonapegsomatropin vs. Daily somatropin							
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )				
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL											
Treatment emergent adverse events (TEAE)	85.3% (78.5, 90.2)	78.7% (68.0, 86.5)	P=0.000, I <sup>2</sup> =91.6%	P=0.001, I <sup>2</sup> =88%	1.720 (0.789, 3.750)	1.088 (0.957, 1.236) 0.198	0.069 (-0.034 - 0.171)	P=0.521, I <sup>2</sup> =0%	P=0.446, I <sup>2</sup> =0%	P=0.611, I <sup>2</sup> =0%	
TEAEs related to study drug	29.4% (22.5, 37.3)	21.3% (13.5, 32.0)	P=0.000, I <sup>2</sup> =95.4%	P=0.045, I <sup>2</sup> =72%							
Serious AEs	3.5% (1.5, 8.1)	1.3% (0.2, 8.9)	P=0.192, I <sup>2</sup> =27.5%	P=0.260, I <sup>2</sup> =0%	2.748 (0.311, 24.304)	2.654 (0.318, 22.165) 0.367	0.022 (-0.018 - 0.061)	P=0.696, I <sup>2</sup> =0%	P=0.703, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	

Table 1.14.m Summary of Adverse Events, subgroup analysis by baseline GH-stimulation strata

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
	Baseline GH-stimulation strata: > 5 ng/mL										
Serious AEs related to study drug	0.7% (0.1, 4.8)	0.0% (0.0, 100.0)	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
TEAEs leading to any action on study drug	11.9% (7.5, 18.3)	12.0% (6.4, 21.5)	P=0.001, I <sup>2</sup> =86.6%	P=0.000, I <sup>2</sup> =0%							
TEAEs leading to discontinu ation of study drug	1.4% (0.4, 5.4)	0.0% (0.0, 100.0)	P=0.106, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.14.m Summary of Adverse Events, subgroup analysis by baseline GH-stimulation strata

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL											
TEAEs leading to death	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.											

Table 1.15.m Summary of Adverse Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin									
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )				
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic											
Treatment emergent adverse events (TEAE)	88.1% (81.9, 92.4)	83.3% (73.8, 89.9)	P=0.000, I <sup>2</sup> =90.7%	P=0.004, I <sup>2</sup> =85%	1.577 (0.707, 3.518)	1.060 (0.952, 1.179) 0.288	0.050 (-0.041 - 0.140)	P=0.502, I <sup>2</sup> =0%	P=0.657, I <sup>2</sup> =0%	P=0.775, I <sup>2</sup> =0%	P=0.644
TEAEs related to study drug	29.1% (22.4, 36.9)	23.8% (15.9, 34.1)	P=0.000, I <sup>2</sup> =94.5%	P=0.044, I <sup>2</sup> =73%							
Serious AEs	3.3% (1.4, 7.7)	2.4% (0.6, 9.0)	P=0.233, I <sup>2</sup> =14.4%	P=0.124, I <sup>2</sup> =0%	1.429 (0.268, 7.627)	1.408 (0.281, 7.054) 0.677	0.010 (-0.033 - 0.053)	P=0.785, I <sup>2</sup> =0%	P=0.783, I <sup>2</sup> =0%	P=0.908, I <sup>2</sup> =0%	P=0.520

Table 1.15.m Summary of Adverse Events, subgroup analysis by etiology and extend of GHD

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic											
Serious AEs related to study drug	0.7% (0.1, 4.5)	0.0% (0.0, 100.0)	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
TEAEs leading to any action on study drug	12.6% (8.2, 18.9)	16.7% (10.1, 26.2)	P=0.001, I <sup>2</sup> =87.1%	P=0.000, I <sup>2</sup> =0%							
TEAEs leading to discontinu ation of study drug	1.3% (0.3, 5.1)	0.0% (0.0, 100.0)	P=0.120, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.500

Table 1.15.m Summary of Adverse Events, subgroup analysis by etiology and extend of GHD

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic											
TEAEs leading to death	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.15.m Summary of Adverse Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction	
Isolated organic												
Treatment emergent adverse events (TEAE)	87.9% (71.8, 95.4)	64.3% (37.6, 84.3)	P=0.028, I <sup>2</sup> =0%	P=0.015, I <sup>2</sup> =0%	4.688 (0.843, 26.076)	1.329 (0.913, 1.936) 0.138	0.215 (-0.041 - 0.472)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%		
TEAEs related to study drug	39.4% (24.4, 56.6)	42.9% (20.6, 68.4)	P=0.011, I <sup>2</sup> =82.8%	P=0.334, I <sup>2</sup> =0%								
Serious AEs	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%		

Table 1.15.m Summary of Adverse Events, subgroup analysis by etiology and extend of GHD

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic											
Serious AEs related to study drug	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
TEAEs leading to any action on study drug	3.0% (0.4, 18.6)	0.0% (0.0, 100.0)	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
TEAEs leading to discontinuation of study drug	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.15.m Summary of Adverse Events, subgroup analysis by etiology and extend of GHD

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic											
TEAEs leading to death	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.15.m Summary of Adverse Events, subgroup analysis by etiology and extend of GHD

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
	Multiple pituitary hormone deficiencies										
Treatment emergent adverse events (TEAE)	81.0% (58.8, 92.7)	90.9% (56.1, 98.7)	P=0.240, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	0.389 (0.037, 4.061)	0.880 (0.663, 1.167) 0.374	-0.109 (-0.348 - 0.129)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
TEAEs related to study drug	14.3% (4.7, 36.1)	27.3% (9.0, 58.6)	P=0.017, I <sup>2</sup> =79.4%	P=0.090, I <sup>2</sup> =0%							
Serious AEs	0.0% (0.0, 100.0)	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.15.m Summary of Adverse Events, subgroup analysis by etiology and extend of GHD

					Lonapegsomatropin vs. Daily somatropin						
	Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies											
Serious AEs related to study drug	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
TEAEs leading to any action on study drug	4.8% (0.7, 27.1)	18.2% (4.6, 50.7)	P=0.040, I <sup>2</sup> =0%	P=0.047, I <sup>2</sup> =0%							
TEAEs leading to discontinu ation of study drug	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.15.m Summary of Adverse Events, subgroup analysis by etiology and extend of GHD

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies											
TEAEs leading to death	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.											

Table 1.16.m Summary of Adverse Events, subgroup analysis by peak stimulated GH concentration at baseline

				Lonapegsomatropin vs. Daily somatropin							
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )				
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL											
Treatment emergent adverse events (TEAE)	83.4% (75.1, 89.4)	79.6% (67.7, 87.9)	P=0.004, I <sup>2</sup> =87.9%	P=0.019, I <sup>2</sup> =82%	1.450 (0.646, 3.253)	1.050 (0.940, 1.173) 0.388	0.042 (-0.052 - 0.135)	P=0.766, I <sup>2</sup> =0%	P=0.555, I <sup>2</sup> =0%	P=0.645, I <sup>2</sup> =0%	P=0.491
TEAEs related to study drug	32.8% (25.0, 41.7)	29.7% (20.5, 40.9)	P=0.000, I <sup>2</sup> =94.4%	P=0.149, I <sup>2</sup> =52%							
Serious AEs	4.2% (1.8, 9.7)	4.1% (1.3, 11.9)	P=0.185, I <sup>2</sup> =43.1%	P=0.522, I <sup>2</sup> =0%	0.889 (0.205, 3.848)	0.894 (0.221, 3.621) 0.875	-0.004 (-0.055 - 0.047)	P=0.677, I <sup>2</sup> =0%	P=0.675, I <sup>2</sup> =0%	P=0.754, I <sup>2</sup> =0%	P=0.743

Table 1.16.m Summary of Adverse Events, subgroup analysis by peak stimulated GH concentration at baseline

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
	Peak stimulated GH concentration at baseline: < 8 ng/mL										
Serious AEs related to study drug	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							
TEAEs leading to any action on study drug	15.1% (9.4, 23.3)	25.3% (15.1, 39.3)	P=0.004, I <sup>2</sup> =87.6%	P=0.006, I <sup>2</sup> =87%							
TEAEs leading to discontinuation of study drug	2.1% (0.6, 7.0)	1.2% (0.2, 8.2)	P=0.349, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.579



Table 1.16.m Summary of Adverse Events, subgroup analysis by peak stimulated GH concentration at baseline

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
	Peak stimulated GH concentration at baseline: < 8 ng/mL										
TEAEs leading to death	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							

Table 1.16.m Summary of Adverse Events, subgroup analysis by peak stimulated GH concentration at baseline

				Lonapegsomatropin vs. Daily somatropin							
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )				
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL											
Treatment emergent adverse events (TEAE)	77.0% (60.5, 88.0)	70.4% (48.6, 85.6)	P=0.036, I <sup>2</sup> =77.2%	P=0.054, I <sup>2</sup> =73%	2.153 (0.615, 7.531)	1.124 (0.914, 1.383) 0.267	0.095 (-0.067 - 0.258)	P=0.485, I <sup>2</sup> =0%	P=0.605, I <sup>2</sup> =0%	P=0.760, I <sup>2</sup> =0%	
TEAEs related to study drug	38.3% (24.5, 54.3)	24.6% (11.2, 45.8)	P=0.001, I <sup>2</sup> =90.5%	P=0.097, I <sup>2</sup> =64%							
Serious AEs	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.16.m Summary of Adverse Events, subgroup analysis by peak stimulated GH concentration at baseline

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
	Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL										
Serious AEs related to study drug	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
TEAEs leading to any action on study drug	13.8% (6.0, 28.4)	15.1% (5.3, 36.0)	P=0.096, I <sup>2</sup> =63.8%	P=0.194, I <sup>2</sup> =41%							
TEAEs leading to discontinu ation of study drug	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.16.m Summary of Adverse Events, subgroup analysis by peak stimulated GH concentration at baseline

					Lonapegsomatropin vs. Daily somatropin						
Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
% of Subjects with	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL											
TEAEs leading to death	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.											

Table 1.24.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin in	Daily somatropin in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years												
Any adverse event		91.0% (81.5, 95.9)	86.1% (70.7, 94.1)	P=0.015, I <sup>2</sup> =76.5%	P=0.042, I <sup>2</sup> =69%	1.672 (0.439, 6.365)	1.054 (0.913, 1.216) 0.477	0.046 (-0.079 - 0.172)	P=0.903, I <sup>2</sup> =0%	P=0.517, I <sup>2</sup> =0%	P=0.576, I <sup>2</sup> =0%	P=0.681
Infections and infestations		70.1% (58.2, 79.9)	77.8% (61.5, 88.5)	P=0.165, I <sup>2</sup> =48.1%	P=0.124, I <sup>2</sup> =56%	0.649 (0.246, 1.708)	0.898 (0.715, 1.129) 0.358	-0.079 (-0.250 - 0.091)	P=0.616, I <sup>2</sup> =0%	P=0.833, I <sup>2</sup> =0%	P=0.748, I <sup>2</sup> =0%	P=0.783
Infections and infestations	Upper respiratory tract infection	34.3% (24.0, 46.4)	52.8% (36.7, 68.3)	P=0.000, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%	0.191 (0.049, 0.745)	0.634 (0.460, 0.874) 0.005	-0.195 (-0.339 - -0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.313

Table 1.24.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years												
Infections and infestations	Pharyngitis	6.0% (2.3, 14.9)	8.3% (2.7, 22.9)	P=0.004, I <sup>2</sup> =0%	P=0.013, I <sup>2</sup> =0%	0.698 (0.132, 3.692)	0.747 (0.194, 2.870) 0.671	-0.021 (-0.121 - 0.079)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.577
Infections and infestations	Nasopharyngitis	6.0% (2.3, 14.9)	5.6% (1.4, 19.7)	P=0.004, I <sup>2</sup> =0%	P=0.046, I <sup>2</sup> =0%	1.143 (0.182, 7.193)	1.120 (0.234, 5.363) 0.887	0.007 (-0.083 - 0.096)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.667
Infections and infestations	Bronchitis	14.9% (8.2, 25.6)	11.1% (4.2, 26.1)	P=0.202, I <sup>2</sup> =29.6%	P=0.633, I <sup>2</sup> =0%	1.390 (0.405, 4.762)	1.337 (0.446, 4.007) 0.605	0.037 (-0.097 - 0.171)	P=0.264, I <sup>2</sup> =1970%	P=0.270, I <sup>2</sup> =1772%	P=0.240, I <sup>2</sup> =2754%	P=0.575
Infections and infestations	Respiratory tract infection	6.0% (2.3, 14.9)	2.8% (0.4, 17.3)	P=0.004, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%	2.476 (0.249, 24.646)	2.240 (0.277, 18.135) 0.45	0.034 (-0.042 - 0.109)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.513

Table 1.24.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years												
Infections and infestations	Rhinitis	1.5% (0.2, 9.8)	5.6% (1.4, 19.7)	P=0.158, I <sup>2</sup> =0%	P=0.046, I <sup>2</sup> =0%	0.250 (0.021, 3.041)	0.280 (0.028, 2.820) 0.28	-0.039 (-0.118 - 0.039)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.781
Respiratory, thoracic and mediastinal disorders		38.8% (28.0, 50.9)	16.7% (7.7, 32.5)	P=0.375, I <sup>2</sup> =0%	P=0.199, I <sup>2</sup> =26%	3.223 (1.164, 8.927)	2.310 (1.057, 5.046) 0.036	0.219 (0.052 - 0.386)	P=0.488, I <sup>2</sup> =0%	P=0.419, I <sup>2</sup> =0%	P=0.768, I <sup>2</sup> =0%	P=0.213
Respiratory, thoracic and mediastinal disorders	Cough	28.4% (18.9, 40.2)	8.3% (2.7, 22.9)	P=0.075, I <sup>2</sup> =65%	P=0.077, I <sup>2</sup> =0%	4.653 (1.221, 17.730)	3.348 (1.087, 10.316) 0.035	0.197 (0.060 - 0.335)	P=0.663, I <sup>2</sup> =0%	P=0.601, I <sup>2</sup> =0%	P=0.486, I <sup>2</sup> =0%	P=0.230

Table 1.24.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years												
Investigations		35.8% (25.3, 47.9)	25.0% (13.6, 41.5)	P=0.000, I <sup>2</sup> =0%	P=0.001, I <sup>2</sup> =0%	1.926 (0.676, 5.486)	1.397 (0.793, 2.461) 0.247	0.100 (-0.055 - 0.256)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.049
Investigations	Blood glucose increased	6.0% (2.3, 14.9)	11.1% (4.2, 26.1)	P=0.049, I <sup>2</sup> =0%	P=0.039, I <sup>2</sup> =0%	0.474 (0.106, 2.112)	0.524 (0.145, 1.896) 0.324	-0.053 (-0.168 - 0.061)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.929
Investigations	Insulin-like growth factor increased	25.4% (16.4, 37.1)	2.8% (0.4, 17.3)	P=0.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	14.280 (1.751, 116.447)	8.905 (1.267, 62.570) 0.028	0.222 (0.108 - 0.336)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.544
Investigations	Blood alkaline phosphatase increased	3.0% (0.7, 11.2)	8.3% (2.7, 22.9)	P=0.168, I <sup>2</sup> =0%	P=0.077, I <sup>2</sup> =0%	0.317 (0.049, 2.056)	0.349 (0.063, 1.937) 0.229	-0.055 (-0.153 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.830



Table 1.24.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years												
Gastrointestinal disorders		16.4% (9.3, 27.3)	16.7% (7.7, 32.5)	P=0.203, I <sup>2</sup> =38.1%	P=0.010, I <sup>2</sup> =0%	0.981 (0.341, 2.822)	0.984 (0.390, 2.479) 0.972	-0.003 (-0.158 - 0.153)	P=0.034, I <sup>2</sup> =7778%	P=0.040, I <sup>2</sup> =7638%	P=0.008, I <sup>2</sup> =8596%	P=0.312
General disorders and administration site conditions		17.9% (10.5, 28.9)	13.9% (5.9, 29.3)	P=0.319, I <sup>2</sup> =0%	P=0.331, I <sup>2</sup> =0%	1.344 (0.429, 4.215)	1.277 (0.493, 3.309) 0.615	0.039 (-0.106 - 0.183)	P=0.790, I <sup>2</sup> =0%	P=0.772, I <sup>2</sup> =0%	P=0.904, I <sup>2</sup> =0%	P=0.415
General disorders and administration site conditions	Pyrexia	10.4% (5.1, 20.3)	8.3% (2.7, 22.9)	P=0.008, I <sup>2</sup> =0%	P=0.077, I <sup>2</sup> =0%	1.267 (0.293, 5.472)	1.222 (0.350, 4.267) 0.753	0.019 (-0.094 - 0.131)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.842

Table 1.24.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years												
Nervous system disorders		0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.960
Nervous system disorders	Headache	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.856
Metabolism and nutrition disorders		10.4% (5.1, 20.3)	2.8% (0.4, 17.3)	P=0.008, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	4.200 (0.482, 36.565)	3.667 (0.481, 27.941) 0.21	0.075 (-0.014 - 0.164)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.081

Table 1.24.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years												
Injury, poisoning and procedural complications		0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.682
Musculoskeletal and connective tissue disorders		1.5% (0.2, 9.8)	5.6% (1.4, 19.7)	P=0.158, I <sup>2</sup> =0%	P=0.046, I <sup>2</sup> =0%	0.250 (0.021, 3.041)	0.280 (0.028, 2.820) 0.28	-0.039 (-0.118 - 0.039)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.293
Endocrine disorders		0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.797
Eye disorders		0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.455

Table 1.24.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years												
Skin and subcutaneous tissue disorders		11.9% (6.1, 22.1)	2.8% (0.4, 17.3)	P=0.991, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%	4.820 (0.568, 40.929)	4.361 (0.558, 34.072) 0.16	0.092 (-0.002 - 0.186)	P=0.393, I <sup>2</sup> =0%	P=0.375, I <sup>2</sup> =0%	P=0.605, I <sup>2</sup> =0%	P=0.335
Blood and lymphatic system disorders		4.5% (1.5, 13.0)	0.0% (0.0, 100.0)	P=0.013, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.046 (-0.004 - 0.096)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.481

Table 1.24.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years												
Any adverse event		85.5% (78.6, 90.5)	79.5% (68.7, 87.2)	P=0.000, I <sup>2</sup> =86.9%	P=0.007, I <sup>2</sup> =82%	1.607 (0.736, 3.508)	1.078 (0.947, 1.227) 0.259	0.062 (-0.043 - 0.166)	P=0.445, I <sup>2</sup> =0%	P=0.587, I <sup>2</sup> =0%	P=0.745, I <sup>2</sup> =0%	
Infections and infestations		50.0% (41.7, 58.3)	53.4% (42.0, 64.5)	P=0.730, I <sup>2</sup> =0%	P=0.790, I <sup>2</sup> =0%	0.871 (0.493, 1.538)	0.936 (0.713, 1.227) 0.631	-0.034 (-0.176 - 0.107)	P=0.990, I <sup>2</sup> =0%	P=0.998, I <sup>2</sup> =0%	P=0.990, I <sup>2</sup> =0%	
Infections and infestations	Upper respiratory tract infection	18.1% (12.5, 25.4)	21.9% (13.9, 32.8)	P=0.000, I <sup>2</sup> =94%	P=0.016, I <sup>2</sup> =81%	0.772 (0.365, 1.633)	0.832 (0.492, 1.408) 0.493	-0.037 (-0.145 - 0.071)	P=0.246, I <sup>2</sup> =2569%	P=0.206, I <sup>2</sup> =3740%	P=0.476, I <sup>2</sup> =0%	

Table 1.24.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years												
Infections and infestations	Pharyngitis	4.3% (2.0, 9.3)	9.6% (4.6, 18.8)	P=0.009, I <sup>2</sup> =0%	P=0.004, I <sup>2</sup> =0%	0.405 (0.127, 1.296)	0.450 (0.162, 1.254) 0.127	-0.053 (-0.127 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Nasopharyngitis	5.8% (2.9, 11.2)	8.2% (3.7, 17.1)	P=0.003, I <sup>2</sup> =0%	P=0.008, I <sup>2</sup> =0%	0.667 (0.215, 2.067)	0.700 (0.260, 1.885) 0.48	-0.025 (-0.097 - 0.047)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Bronchitis	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Respiratory tract infection	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.24.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years												
Infections and infestations	Rhinitis	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders		24.6% (18.2, 32.5)	20.5% (12.8, 31.3)	P=0.777, I <sup>2</sup> =0%	P=0.342, I <sup>2</sup> =0%	1.266 (0.636, 2.521)	1.200 (0.702, 2.053) 0.505	0.041 (-0.076 - 0.158)	P=0.533, I <sup>2</sup> =0%	P=0.520, I <sup>2</sup> =0%	P=0.564, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Cough	8.7% (5.0, 14.7)	6.8% (2.9, 15.4)	P=0.000, I <sup>2</sup> =0%	P=0.003, I <sup>2</sup> =0%	1.357 (0.430, 4.279)	1.283 (0.497, 3.309) 0.607	0.019 (-0.051 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.24.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years												
Investigations		18.8% (13.2, 26.2)	27.4% (18.4, 38.7)	P=0.000, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%	0.447 (0.182, 1.099)	0.695 (0.472, 1.023) 0.065	-0.083 (-0.178 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood glucose increased	9.4% (5.5, 15.5)	19.2% (11.7, 29.8)	P=0.000, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%	0.351 (0.137, 0.897)	0.496 (0.268, 0.919) 0.026	-0.096 (-0.189 - -0.004)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Insulin-like growth factor increased	8.7% (5.0, 14.7)	2.7% (0.7, 10.3)	P=0.000, I <sup>2</sup> =0%	P=0.061, I <sup>2</sup> =0%	3.783 (0.789, 18.135)	3.207 (0.766, 13.428) 0.111	0.060 (0.002 - 0.118)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood alkaline phosphatase increased	0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.24.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years												
Gastrointestinal disorders		21.7% (15.6, 29.4)	19.2% (11.7, 29.8)	P=0.799, I <sup>2</sup> =0%	P=0.974, I <sup>2</sup> =0%	1.170 (0.576, 2.379)	1.133 (0.642, 1.999) 0.666	0.026 (-0.088 - 0.139)	P=0.863, I <sup>2</sup> =0%	P=0.865, I <sup>2</sup> =0%	P=0.857, I <sup>2</sup> =0%	
General disorders and administration site conditions		18.8% (13.2, 26.2)	23.3% (15.0, 34.3)	P=0.975, I <sup>2</sup> =0%	P=0.321, I <sup>2</sup> =0%	0.765 (0.384, 1.527)	0.810 (0.471, 1.392) 0.445	-0.044 (-0.161 - 0.073)	P=0.448, I <sup>2</sup> =0%	P=0.459, I <sup>2</sup> =0%	P=0.421, I <sup>2</sup> =0%	
General disorders and administration site conditions	Pyrexia	16.7% (11.3, 23.8)	12.3% (6.5, 22.0)	P=0.757, I <sup>2</sup> =0%	P=0.399, I <sup>2</sup> =0%	1.422 (0.621, 3.255)	1.352 (0.660, 2.773) 0.41	0.043 (-0.054 - 0.141)	P=0.382, I <sup>2</sup> =0%	P=0.379, I <sup>2</sup> =0%	P=0.398, I <sup>2</sup> =0%	

Table 1.24.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin in	Daily somatropin in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years												
Nervous system disorders		10.9% (6.7, 17.2)	19.2% (11.7, 29.8)	P=0.011, I <sup>2</sup> =78.7%	P=0.567, I <sup>2</sup> =0%	0.507 (0.228, 1.129)	0.565 (0.290, 1.100) 0.093	-0.084 (-0.187 - 0.020)	P=0.177, I <sup>2</sup> =4523%	P=0.155, I <sup>2</sup> =5058%	P=0.456, I <sup>2</sup> =0%	
Nervous system disorders	Headache	8.7% (5.0, 14.7)	15.1% (8.5, 25.2)	P=0.000, I <sup>2</sup> =0%	P=0.655, I <sup>2</sup> =0%	0.529 (0.218, 1.282)	0.574 (0.268, 1.231) 0.154	-0.064 (-0.158 - 0.030)	P=0.068, I <sup>2</sup> =6994%	P=0.065, I <sup>2</sup> =7061%	P=0.200, I <sup>2</sup> =3899%	
Metabolism and nutrition disorders		3.6% (1.5, 8.4)	9.6% (4.6, 18.8)	P=0.003, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%	0.323 (0.093, 1.123)	0.382 (0.132, 1.104) 0.075	-0.059 (-0.131 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.24.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years												
Injury, poisoning and procedural complications		8.7% (5.0, 14.7)	8.2% (3.7, 17.1)	P=0.000, I <sup>2</sup> =0%	P=0.008, I <sup>2</sup> =0%	1.059 (0.367, 3.056)	1.050 (0.424, 2.598) 0.916	0.004 (-0.072 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders		6.5% (3.4, 12.1)	5.5% (2.1, 13.7)	P=0.001, I <sup>2</sup> =0%	P=0.032, I <sup>2</sup> =0%	1.204 (0.348, 4.169)	1.181 (0.387, 3.610) 0.77	0.010 (-0.055 - 0.075)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders		5.8% (2.9, 11.2)	6.8% (2.9, 15.4)	P=0.003, I <sup>2</sup> =0%	P=0.016, I <sup>2</sup> =0%	0.822 (0.251, 2.691)	0.840 (0.293, 2.408) 0.746	-0.011 (-0.079 - 0.057)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders		5.8% (2.9, 11.2)	2.7% (0.7, 10.3)	P=0.000, I <sup>2</sup> =0%	P=0.061, I <sup>2</sup> =0%	2.320 (0.461, 11.672)	2.138 (0.483, 9.456) 0.317	0.031 (-0.021 - 0.084)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.24.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years												
Skin and subcutaneous tissue disorders		0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders		0.0% (0.0, 100.0)	0.0% (0.0, 100.0)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.												

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Any adverse event		87.9% (82.1, 92.0)	83.5% (74.4, 89.8)	P=0.000, I <sup>2</sup> =0%	P=0.001, I <sup>2</sup> =86%	1.470 (0.681, 3.173)	1.050 (0.949, 1.161) 0.346	0.041 (-0.044 - 0.127)	P=0.189, I <sup>2</sup> =4202%	P=0.952, I <sup>2</sup> =0%	P=0.830, I <sup>2</sup> =0%	P=0.868
Infections and infestations		56.6% (49.2, 63.8)	61.5% (51.2, 70.9)	P=0.147, I <sup>2</sup> =52.1%	P=0.573, I <sup>2</sup> =0%	0.813 (0.483, 1.368)	0.919 (0.747, 1.131) 0.427	-0.050 (-0.174 - 0.074)	P=0.703, I <sup>2</sup> =0%	P=0.639, I <sup>2</sup> =0%	P=0.683, I <sup>2</sup> =0%	P=0.870
Infections and infestations	Upper respiratory tract infection	26.0% (20.0, 33.1)	33.0% (24.1, 43.2)	P=0.000, I <sup>2</sup> =96%	P=0.000, I <sup>2</sup> =94%	0.641 (0.343, 1.200)	0.780 (0.554, 1.098) 0.154	-0.073 (-0.177 - 0.031)	P=0.940, I <sup>2</sup> =0%	P=0.698, I <sup>2</sup> =0%	P=0.460, I <sup>2</sup> =0%	P=0.582

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Infections and infestations	Nasopharyngitis	6.4% (3.6, 11.1)	7.7% (3.7, 15.3)	P=0.000, I <sup>2</sup> =0%	P=0.001, I <sup>2</sup> =0%	0.817 (0.294, 2.274)	0.841 (0.350, 2.021) 0.698	-0.012 (-0.075 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.459
Infections and infestations	Pharyngitis	3.5% (1.6, 7.5)	9.9% (5.2, 17.9)	P=0.003, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%	0.308 (0.102, 0.930)	0.357 (0.135, 0.940) 0.037	-0.063 (-0.129 - 0.002)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.290
Infections and infestations	Gastroenteritis	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.822
Infections and infestations	Respiratory tract infection	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.810

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin in	Daily somatropin in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Infections and infestations	Viral infection	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.466
Infections and infestations	Ear infection	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.975
Infections and infestations	Enterobiasis	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.550

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Infections and infestations	Pharyngotonsillitis	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.975
Infections and infestations	Urinary tract infection	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.584
Infections and infestations	Bronchitis	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.763
Infections and infestations	Croup infectious	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.763



Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Infections and infestations	Hordeolum	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.763
Infections and infestations	Pharyngitis streptococcal	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.763
Infections and infestations	Sinusitis	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.763
Infections and infestations	Viral upper respiratory tract infection	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.763

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Infections and infestations	Conjunctivitis	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.773
Investigations		27.2% (21.1, 34.3)	27.5% (19.3, 37.5)	P=0.000, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%	0.940 (0.456, 1.938)	0.972 (0.702, 1.346) 0.866	-0.008 (-0.097 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.433
Investigations	Blood glucose increased	9.8% (6.2, 15.2)	15.4% (9.3, 24.3)	P=0.000, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%	0.538 (0.236, 1.226)	0.628 (0.342, 1.155) 0.134	-0.058 (-0.138 - 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.220
Investigations	Insulin-like growth factor increased	15.0% (10.4, 21.2)	2.2% (0.6, 8.4)	P=0.000, I <sup>2</sup> =0%	P=0.091, I <sup>2</sup> =0%	9.164 (2.065, 40.671)	6.724 (1.671, 27.063) 0.007	0.127 (0.067 - 0.186)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.265

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Investigations	Cortisol decreased	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.951
Investigations	Alanine aminotransferase increased	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.763
Investigations	Aspartate aminotransferase increased	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.763

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatropin in Mean (95%CI)	Daily somatropin in Mean (95%CI)	Lonapeg somatropin in	Daily somatropin in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Investigations	Blood glucose abnormal	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.773
Investigations	Liver function test abnormal	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.773
Respiratory, thoracic and mediastinal disorders		29.5% (23.2, 36.7)	22.0% (14.6, 31.6)	P=0.263, I <sup>2</sup> =19.7%	P=0.113, I <sup>2</sup> =59%	1.486 (0.817, 2.703)	1.337 (0.855, 2.091) 0.203	0.074 (-0.034 - 0.182)	P=0.478, I <sup>2</sup> =0%	P=0.432, I <sup>2</sup> =0%	P=0.586, I <sup>2</sup> =0%	P=0.263
Respiratory, thoracic and mediastinal disorders	Cough	13.3% (9.0, 19.2)	8.8% (4.5, 16.6)	P=0.000, I <sup>2</sup> =0%	P=0.001, I <sup>2</sup> =0%	1.662 (0.675, 4.091)	1.487 (0.724, 3.054) 0.28	0.043 (-0.029 - 0.115)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.271

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Respiratory, thoracic and mediastinal disorders	Epistaxis	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.763
Respiratory, thoracic and mediastinal disorders	Nasal congestion	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.763
Gastrointestinal disorders		19.1% (13.9, 25.6)	18.7% (11.9, 28.0)	P=0.314, I <sup>2</sup> =0.2%	P=0.161, I <sup>2</sup> =47%	1.026 (0.538, 1.956)	1.021 (0.602, 1.733) 0.938	0.004 (-0.096 - 0.104)	P=0.088, I <sup>2</sup> =6559%	P=0.090, I <sup>2</sup> =6522%	P=0.082, I <sup>2</sup> =6699%	P=0.551
Gastrointestinal disorders	Diarrhoea	2.9% (1.2, 6.8)	5.5% (2.3, 12.5)	P=0.008, I <sup>2</sup> =0%	P=0.007, I <sup>2</sup> =0%	0.488 (0.133, 1.783)	0.517 (0.158, 1.694) 0.276	-0.027 (-0.079 - 0.025)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.616

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Gastrointestin al disorders	Vomiting	5.2% (2.7, 9.7)	1.1% (0.2, 7.4)	P=0.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	5.260 (0.645, 42.886)	4.814 (0.629, 36.827) 0.13	0.042 (0.003 - 0.081)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.079
Gastrointestin al disorders	Abdominal pain upper	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.975
Gastrointestin al disorders	Abdominal pain	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.951
Gastrointestin al disorders	Nausea	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.763

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male												
General disorders and administration site conditions		19.7% (14.4, 26.2)	18.7% (11.9, 28.0)	P=0.466, I <sup>2</sup> =0%	P=0.161, I <sup>2</sup> =47%	1.061 (0.554, 2.032)	1.049 (0.623, 1.767) 0.858	0.009 (-0.090 - 0.108)	P=0.471, I <sup>2</sup> =0%	P=0.467, I <sup>2</sup> =0%	P=0.481, I <sup>2</sup> =0%	P=0.213
General disorders and administration site conditions	Pyrexia	16.2% (11.4, 22.4)	12.1% (6.8, 20.5)	P=0.704, I <sup>2</sup> =0%	P=0.094, I <sup>2</sup> =60%	1.401 (0.661, 2.969)	1.334 (0.699, 2.548) 0.382	0.041 (-0.046 - 0.127)	P=0.236, I <sup>2</sup> =2894%	P=0.228, I <sup>2</sup> =3121%	P=0.281, I <sup>2</sup> =1401%	P=0.552

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male												
General disorders and administration site conditions	Medical device discomfort	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.763
General disorders and administration site conditions	Vaccination site pain	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.763
General disorders and administration site conditions	Injection site swelling	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.773



Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male												
General disorders and administration site conditions	Pain	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.773
Nervous system disorders		7.5% (4.4, 12.5)	7.7% (3.7, 15.3)	P=0.000, I <sup>2</sup> =0%	P=0.001, I <sup>2</sup> =0%	0.992 (0.366, 2.691)	0.993 (0.426, 2.315) 0.988	-0.001 (-0.065 - 0.064)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.107
Nervous system disorders	Headache	6.9% (4.0, 11.8)	6.6% (3.0, 13.9)	P=0.000, I <sup>2</sup> =0%	P=0.003, I <sup>2</sup> =0%	1.081 (0.377, 3.098)	1.070 (0.430, 2.664) 0.885	0.005 (-0.057 - 0.066)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.233

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Nervous system disorders	Dizziness	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.838
Injury, poisoning and procedural complications		6.4% (3.6, 11.1)	5.5% (2.3, 12.5)	P=0.000, I <sup>2</sup> =0%	P=0.008, I <sup>2</sup> =0%	1.203 (0.391, 3.699)	1.177 (0.435, 3.182) 0.748	0.010 (-0.048 - 0.067)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.902
Injury, poisoning and procedural complications	Post-traumatic pain	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.763

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Injury, poisoning and procedural complications	Thermal burn	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.763
Metabolism and nutrition disorders		6.9% (4.0, 11.8)	8.8% (4.5, 16.6)	P=0.000, I <sup>2</sup> =0%	P=0.001, I <sup>2</sup> =0%	0.740 (0.278, 1.967)	0.776 (0.342, 1.760) 0.544	-0.020 (-0.086 - 0.047)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.862
Musculoskeletal and connective tissue disorders		5.2% (2.7, 9.7)	5.5% (2.3, 12.5)	P=0.000, I <sup>2</sup> =0%	P=0.008, I <sup>2</sup> =0%	0.958 (0.301, 3.048)	0.963 (0.343, 2.705) 0.943	-0.002 (-0.058 - 0.054)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.684

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Musculoskeletal and connective tissue disorders	Pain in extremity	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.975
Musculoskeletal and connective tissue disorders	Neck pain	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.763
Endocrine disorders		3.5% (1.6, 7.5)	6.6% (3.0, 13.9)	P=0.003, I <sup>2</sup> =0%	P=0.003, I <sup>2</sup> =0%	0.500 (0.152, 1.649)	0.535 (0.183, 1.565) 0.253	-0.030 (-0.087 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.594
Endocrine disorders	Secondary hypothyroidism	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.466

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Endocrine disorders	Precocious puberty	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.773
Eye disorders		5.8% (3.1, 10.4)	3.3% (1.1, 9.7)	P=0.000, I <sup>2</sup> =0%	P=0.037, I <sup>2</sup> =0%	1.818 (0.474, 6.971)	1.724 (0.499, 5.952) 0.389	0.024 (-0.025 - 0.073)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.240
Eye disorders	Vernal keratoconjunctivitis	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.773

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Skin and subcutaneous tissue disorders		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.238
Skin and subcutaneous tissue disorders	Urticaria	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.530
Ear and labyrinth disorders		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.550
Ear and labyrinth disorders	Ear pain	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.550

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.975
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.975

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Vascular disorders		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.550
Vascular disorders	Hypotension	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.550



Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Any adverse event		84.4% (67.5, 93.3)	72.2% (48.1, 87.9)	P=0.975, I <sup>2</sup> =0%	P=0.182, I <sup>2</sup> =34%	2.121 (0.523, 8.609)	1.175 (0.847, 1.630) 0.335	0.125 (-0.117 - 0.368)	P=0.344, I <sup>2</sup> =0%	P=0.206, I <sup>2</sup> =3757%	P=0.229, I <sup>2</sup> =3076%	
Infections and infestations		56.3% (39.0, 72.1)	61.1% (37.9, 80.2)	P=0.341, I <sup>2</sup> =0%	P=0.274, I <sup>2</sup> =12%	0.823 (0.260, 2.605)	0.919 (0.559, 1.511) 0.739	-0.049 (-0.339 - 0.241)	P=0.157, I <sup>2</sup> =5016%	P=0.158, I <sup>2</sup> =4995%	P=0.136, I <sup>2</sup> =5501%	
Infections and infestations	Upper respiratory tract infection	15.6% (6.7, 32.5)	27.8% (12.1, 51.9)	P=0.001, I <sup>2</sup> =0%	P=0.001, I <sup>2</sup> =0%	0.375 (0.061, 2.305)	0.615 (0.257, 1.472) 0.275	-0.103 (-0.302 - 0.095)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Infections and infestations	Nasopharyngitis	3.1% (0.4, 19.1)	11.1% (2.8, 35.2)	P=0.302, I <sup>2</sup> =0%	P=0.867, I <sup>2</sup> =0%	0.250 (0.020, 3.063)	0.271 (0.025, 2.953) 0.284	-0.081 (-0.238 - 0.076)	P=0.615, I <sup>2</sup> =0%	P=0.609, I <sup>2</sup> =0%	P=0.627, I <sup>2</sup> =0%	
Infections and infestations	Pharyngitis	12.5% (4.8, 28.9)	11.1% (2.8, 35.2)	P=0.033, I <sup>2</sup> =0%	P=0.867, I <sup>2</sup> =0%	1.092 (0.180, 6.648)	1.082 (0.210, 5.569) 0.924	0.009 (-0.176 - 0.194)	P=0.216, I <sup>2</sup> =3463%	P=0.227, I <sup>2</sup> =3147%	P=0.195, I <sup>2</sup> =4034%	
Infections and infestations	Gastroenteritis	3.1% (0.4, 19.1)	11.1% (2.8, 35.2)	P=0.302, I <sup>2</sup> =0%	P=0.867, I <sup>2</sup> =0%	0.250 (0.020, 3.063)	0.271 (0.025, 2.953) 0.284	-0.081 (-0.238 - 0.076)	P=0.615, I <sup>2</sup> =0%	P=0.609, I <sup>2</sup> =0%	P=0.627, I <sup>2</sup> =0%	
Infections and infestations	Respiratory tract infection	6.3% (1.6, 21.8)	5.6% (0.8, 30.7)	P=0.140, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	1.114 (0.097, 12.820)	1.114 (0.093, 13.403) 0.932	0.006 (-0.131 - 0.143)	P=0.220, I <sup>2</sup> =3355%	P=0.228, I <sup>2</sup> =3129%	P=0.203, I <sup>2</sup> =3838%	

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Infections and infestations	Viral infection	9.4% (3.1, 25.4)	0%	P=0.068, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.090 (-0.010 - 0.189)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Ear infection	3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	0.500 (0.028, 8.952)	0.526 (0.037, 7.554) 0.637	-0.027 (-0.148 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Enterobiasis	6.3% (1.6, 21.8)	0%	P=0.140, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.060 (-0.023 - 0.142)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Infections and infestations	Pharyngotonsillitis	3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	0.500 (0.028, 8.952)	0.526 (0.037, 7.554) 0.637	-0.027 (-0.148 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Urinary tract infection	0%	11.1% (2.8, 35.2)	P=1.000, I <sup>2</sup> =0%	P=0.867, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.111 (-0.256 - 0.034)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.880, I <sup>2</sup> =0%	
Infections and infestations	Bronchitis	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Croup infectious	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Infections and infestations	Hordeolum	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pharyngitis streptococcal	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Sinusitis	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Viral upper respiratory tract infection	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Infections and infestations	Conjunctivitis	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.054 (-0.158 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations		18.8% (8.7, 35.9)	27.8% (12.1, 51.9)	P=0.606, I <sup>2</sup> =0%	P=0.055, I <sup>2</sup> =67%	0.612 (0.153, 2.452)	0.695 (0.248, 1.946) 0.489	-0.083 (-0.325 - 0.159)	P=0.268, I <sup>2</sup> =1851%	P=0.315, I <sup>2</sup> =99%	P=0.156, I <sup>2</sup> =5031%	
Investigations	Blood glucose increased	0%	22.2% (8.6, 46.5)	P=1.000, I <sup>2</sup> =0%	P=0.005, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.215 (-0.406 - -0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Insulin-like growth factor increased	9.4% (3.1, 25.4)	5.6% (0.8, 30.7)	P=0.015, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	2.100 (0.179, 24.596)	1.846 (0.230, 14.848) 0.564	0.046 (-0.093 - 0.184)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Investigations	Cortisol decreased	3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.174, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	0.583 (0.031, 10.863)	0.615 (0.044, 8.522) 0.717	-0.021 (-0.139 - 0.097)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Alanine aminotransferase increased	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Aspartate aminotransferase increased	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Investigations	Blood glucose abnormal	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.054 (-0.158 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Liver function test abnormal	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.054 (-0.158 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders		28.1% (15.3, 45.8)	5.6% (0.8, 30.7)	P=0.784, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	6.371 (0.751, 54.045)	4.957 (0.699, 35.168) 0.109	0.225 (0.035 - 0.416)	P=0.548, I <sup>2</sup> =0%	P=0.530, I <sup>2</sup> =0%	P=0.598, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Cough	21.9% (10.8, 39.3)	0%	P=0.318, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.222 (0.078 - 0.366)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.354, I <sup>2</sup> =0%	



Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Respiratory, thoracic and mediastinal disorders	Epistaxis	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Nasal congestion	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders		25.0% (13.0, 42.6)	16.7% (5.5, 40.9)	P=0.835, I <sup>2</sup> =0%	P=0.668, I <sup>2</sup> =0%	1.650 (0.377, 7.231)	1.486 (0.452, 4.882) 0.514	0.082 (-0.147 - 0.310)	P=0.806, I <sup>2</sup> =0%	P=0.793, I <sup>2</sup> =0%	P=0.853, I <sup>2</sup> =0%	
Gastrointestinal disorders	Diarrhoea	6.3% (1.6, 21.8)	5.6% (0.8, 30.7)	P=0.140, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	1.059 (0.084, 13.329)	1.053 (0.108, 10.240) 0.965	0.003 (-0.129 - 0.135)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatropin in Mean (95%CI)	Daily somatropin in Mean (95%CI)	Lonapeg somatropin in	Daily somatropin in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Gastrointestinal disorders	Vomiting	0%	11.1% (2.8, 35.2)	P=1.000, I <sup>2</sup> =0%	P=0.110, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.114 (-0.260 - 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Abdominal pain upper	3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	0.500 (0.028, 8.952)	0.526 (0.037, 7.554) 0.637	-0.027 (-0.148 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Abdominal pain	3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.174, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	0.583 (0.031, 10.863)	0.615 (0.044, 8.522) 0.717	-0.021 (-0.139 - 0.097)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Nausea	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female												
General disorders and administration site conditions		12.5% (4.8, 28.9)	27.8% (12.1, 51.9)	P=0.485, I <sup>2</sup> =0%	P=0.813, I <sup>2</sup> =0%	0.361 (0.082, 1.591)	0.442 (0.135, 1.445) 0.177	-0.155 (-0.391 - 0.080)	P=0.730, I <sup>2</sup> =0%	P=0.689, I <sup>2</sup> =0%	P=0.896, I <sup>2</sup> =0%	
General disorders and administration site conditions	Pyrexia	9.4% (3.1, 25.4)	11.1% (2.8, 35.2)	P=0.068, I <sup>2</sup> =0%	P=0.110, I <sup>2</sup> =0%	0.750 (0.104, 5.434)	0.789 (0.157, 3.978) 0.774	-0.024 (-0.194 - 0.146)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin in	Daily somatropin in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female												
General disorders and administration site conditions	Medical device discomfort	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Vaccination site pain	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Injection site swelling	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.054 (-0.158 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female												
General disorders and administration site conditions	Pain	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.054 (-0.158 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Nervous system disorders		6.3% (1.6, 21.8)	27.8% (12.1, 51.9)	P=0.782, I <sup>2</sup> =0%	P=0.411, I <sup>2</sup> =0%	0.174 (0.030, 1.022)	0.229 (0.049, 1.063) 0.06	-0.212 (-0.435 - 0.010)	P=0.796, I <sup>2</sup> =0%	P=0.874, I <sup>2</sup> =0%	P=0.508, I <sup>2</sup> =0%	
Nervous system disorders	Headache	3.1% (0.4, 19.1)	16.7% (5.5, 40.9)	P=0.302, I <sup>2</sup> =0%	P=0.396, I <sup>2</sup> =0%	0.167 (0.016, 1.712)	0.182 (0.018, 1.793) 0.144	-0.135 (-0.318 - 0.049)	P=0.413, I <sup>2</sup> =0%	P=0.415, I <sup>2</sup> =0%	P=0.290, I <sup>2</sup> =1081 %	

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Nervous system disorders	Dizziness	3.1% (0.4, 19.1)	11.1% (2.8, 35.2)	P=0.174, I <sup>2</sup> =0%	P=0.867, I <sup>2</sup> =0%	0.272 (0.023, 3.258)	0.299 (0.031, 2.888) 0.297	-0.078 (-0.235 - 0.080)	P=0.551, I <sup>2</sup> =0%	P=0.535, I <sup>2</sup> =0%	P=0.707, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications		9.4% (3.1, 25.4)	5.6% (0.8, 30.7)	P=0.068, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	1.688 (0.152, 18.714)	1.579 (0.188, 13.283) 0.674	0.033 (-0.109 - 0.175)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Post-traumatic pain	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Injury, poisoning and procedural complications	Thermal burn	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders		3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	0.500 (0.028, 8.952)	0.526 (0.037, 7.554) 0.637	-0.027 (-0.148 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Musculoskeletal and connective tissue disorders	Pain in extremity	3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	0.500 (0.028, 8.952)	0.526 (0.037, 7.554) 0.637	-0.027 (-0.148 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders	Neck pain	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders		9.4% (3.1, 25.4)	5.6% (0.8, 30.7)	P=0.068, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	1.671 (0.170, 16.457)	1.671 (0.161, 17.365) 0.667	0.036 (-0.113 - 0.186)	P=0.149, I <sup>2</sup> =5187%	P=0.155, I <sup>2</sup> =5057%	P=0.126, I <sup>2</sup> =5730%	
Endocrine disorders	Secondary hypothyroidism	9.4% (3.1, 25.4)	0%	P=0.068, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.090 (-0.010 - 0.189)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin in	Daily somatropin in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Endocrine disorders	Precocious puberty	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.054 (-0.158 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders		0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.054 (-0.158 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Vernal keratoconjunctivitis	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.054 (-0.158 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Skin and subcutaneous tissue disorders		18.8% (8.7, 35.9)	0%	P=0.606, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.189 (0.054 - 0.325)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.571, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Urticaria	6.3% (1.6, 21.8)	0%	P=0.051, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.066 (-0.020 - 0.152)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Ear and labyrinth disorders		6.3% (1.6, 21.8)	0%	P=0.140, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.060 (-0.023 - 0.142)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Ear and labyrinth disorders	Ear pain	6.3% (1.6, 21.8)	0%	P=0.140, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.060 (-0.023 - 0.142)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	0.500 (0.028, 8.952)	0.526 (0.037, 7.554) 0.637	-0.027 (-0.148 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	0.500 (0.028, 8.952)	0.526 (0.037, 7.554) 0.637	-0.027 (-0.148 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.25.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Vascular disorders		6.3% (1.6, 21.8)	0%	P=0.140, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.060 (-0.023 - 0.142)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Vascular disorders	Hypotension	6.3% (1.6, 21.8)	0%	P=0.140, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.060 (-0.023 - 0.142)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.												

Table 1.26.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL												
Any adverse event		91.9% (82.0, 96.6)	88.2% (72.5, 95.5)	P=0.020, I <sup>2</sup> =0%	P=0.041, I <sup>2</sup> =0%	1.506 (0.357, 6.358)	1.038 (0.904, 1.192) 0.594	0.034 (-0.090 - 0.157)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.636
Infections and infestations		58.1% (45.5, 69.6)	64.7% (47.6, 78.7)	P=0.065, I <sup>2</sup> =70%	P=0.663, I <sup>2</sup> =0%	0.767 (0.325, 1.809)	0.902 (0.650, 1.250) 0.534	-0.064 (-0.268 - 0.140)	P=0.158, I <sup>2</sup> =4985%	P=0.129, I <sup>2</sup> =5654%	P=0.138, I <sup>2</sup> =5454%	P=0.854
Infections and infestations	Upper respiratory tract infection	16.1% (8.9, 27.5)	35.3% (21.3, 52.4)	P=0.000, I <sup>2</sup> =86.7%	P=0.012, I <sup>2</sup> =83%	0.252 (0.079, 0.803)	0.440 (0.228, 0.849) 0.014	-0.199 (-0.367 - -0.032)	P=0.419, I <sup>2</sup> =0%	P=0.184, I <sup>2</sup> =4345%	P=0.601, I <sup>2</sup> =0%	P=0.189

Table 1.26.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL												
Infections and infestations	Pharyngitis	4.8% (1.6, 14.0)	20.6% (10.1, 37.3)	P=0.074, I <sup>2</sup> =0%	P=0.549, I <sup>2</sup> =0%	0.195 (0.046, 0.832)	0.241 (0.068, 0.854) 0.028	-0.156 (-0.301 - -0.011)	P=0.500, I <sup>2</sup> =0%	P=0.461, I <sup>2</sup> =0%	P=0.972, I <sup>2</sup> =0%	P=0.257
Infections and infestations	Nasopharyngitis	11.3% (5.5, 21.8)	8.8% (2.9, 24.0)	P=0.005, I <sup>2</sup> =0%	P=0.080, I <sup>2</sup> =0%	1.400 (0.321, 6.109)	1.324 (0.382, 4.585) 0.658	0.028 (-0.091 - 0.147)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.303
Infections and infestations	Bronchitis	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.460
Infections and infestations	Tonsillitis	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.975

Table 1.26.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL												
Infections and infestations	Pharyngitis streptococcal	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.422
Respiratory, thoracic and mediastinal disorders		25.8% (16.5, 38.1)	17.6% (8.1, 34.1)	P=0.789, I <sup>2</sup> =0%	P=0.518, I <sup>2</sup> =0%	1.617 (0.568, 4.604)	1.459 (0.631, 3.376) 0.377	0.081 (-0.087 - 0.250)	P=0.491, I <sup>2</sup> =0%	P=0.485, I <sup>2</sup> =0%	P=0.508, I <sup>2</sup> =0%	P=0.877
Respiratory, thoracic and mediastinal disorders	Cough	16.1% (8.9, 27.5)	2.9% (0.4, 18.1)	P=0.499, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	6.440 (0.765, 54.217)	5.352 (0.736, 38.920) 0.098	0.130 (0.023 - 0.237)	P=0.505, I <sup>2</sup> =0%	P=0.481, I <sup>2</sup> =0%	P=0.884, I <sup>2</sup> =0%	P=0.271

Table 1.26.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL												
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.847
Investigations		19.4% (11.3, 31.1)	23.5% (12.2, 40.5)	P=0.000, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%	0.577 (0.147, 2.260)	0.780 (0.431, 1.411) 0.411	-0.053 (-0.186 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.544
Investigations	Blood glucose increased	6.5% (2.4, 16.0)	17.6% (8.1, 34.1)	P=0.006, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%	0.222 (0.048, 1.023)	0.347 (0.119, 1.014) 0.053	-0.117 (-0.248 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.454
Investigations	Insulin-like growth factor increased	11.3% (5.5, 21.8)	2.9% (0.4, 18.1)	P=0.000, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	4.667 (0.507, 42.923)	3.640 (0.500, 26.501) 0.202	0.079 (-0.013 - 0.171)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.604



Table 1.26.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatropin in Mean (95%CI)	Daily somatropin in Mean (95%CI)	Lonapeg somatropin in	Daily somatropin in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL												
Investigations	Blood alkaline phosphatase increased	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.691
Gastrointestinal disorders		30.6% (20.5, 43.1)	17.6% (8.1, 34.1)	P=0.849, I <sup>2</sup> =0%	P=0.518, I <sup>2</sup> =0%	2.054 (0.730, 5.783)	1.729 (0.766, 3.902) 0.188	0.129 (-0.043 - 0.301)	P=0.651, I <sup>2</sup> =0%	P=0.624, I <sup>2</sup> =0%	P=0.721, I <sup>2</sup> =0%	P=0.153
Gastrointestinal disorders	Diarrhoea	4.8% (1.6, 14.0)	2.9% (0.4, 18.1)	P=0.017, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	1.636 (0.153, 17.504)	1.560 (0.180, 13.549) 0.687	0.017 (-0.059 - 0.092)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.356
Gastrointestinal disorders	Vomiting	6.5% (2.4, 16.0)	2.9% (0.4, 18.1)	P=0.038, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	2.424 (0.253, 23.246)	2.270 (0.271, 19.006) 0.449	0.037 (-0.045 - 0.119)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.510

Table 1.26.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL												
General disorders and administration site conditions		21.0% (12.6, 32.8)	14.7% (6.3, 30.8)	P=0.424, I <sup>2</sup> =0%	P=0.930, I <sup>2</sup> =0%	1.547 (0.501, 4.776)	1.433 (0.559, 3.672) 0.454	0.064 (-0.093 - 0.220)	P=0.609, I <sup>2</sup> =0%	P=0.622, I <sup>2</sup> =0%	P=0.560, I <sup>2</sup> =0%	P=0.277
General disorders and administration site conditions	Pyrexia	19.4% (11.3, 31.1)	2.9% (0.4, 18.1)	P=0.579, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	8.254 (0.998, 68.256)	6.686 (0.902, 49.541) 0.063	0.165 (0.052 - 0.278)	P=0.658, I <sup>2</sup> =0%	P=0.662, I <sup>2</sup> =0%	P=0.753, I <sup>2</sup> =0%	P=0.064
Nervous system disorders		8.1% (3.4, 18.0)	20.6% (10.1, 37.3)	P=0.313, I <sup>2</sup> =0%	P=0.779, I <sup>2</sup> =0%	0.344 (0.100, 1.179)	0.396 (0.136, 1.148) 0.088	-0.125 (-0.277 - 0.028)	P=0.361, I <sup>2</sup> =0%	P=0.352, I <sup>2</sup> =0%	P=0.494, I <sup>2</sup> =0%	P=0.247

Table 1.26.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL												
Nervous system disorders	Headache	6.5% (2.4, 16.0)	14.7% (6.3, 30.8)	P=0.038, I <sup>2</sup> =0%	P=0.930, I <sup>2</sup> =0%	0.411 (0.102, 1.646)	0.448 (0.130, 1.543) 0.203	-0.081 (-0.216 - 0.053)	P=0.237, I <sup>2</sup> =2845%	P=0.232, I <sup>2</sup> =2991%	P=0.371, I <sup>2</sup> =0%	P=0.391
Injury, poisoning and procedural complications		8.1% (3.4, 18.0)	5.9% (1.5, 20.7)	P=0.020, I <sup>2</sup> =0%	P=0.157, I <sup>2</sup> =0%	1.484 (0.262, 8.417)	1.419 (0.301, 6.685) 0.658	0.024 (-0.077 - 0.126)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.890
Metabolism and nutrition disorders		4.8% (1.6, 14.0)	8.8% (2.9, 24.0)	P=0.017, I <sup>2</sup> =0%	P=0.012, I <sup>2</sup> =0%	0.455 (0.078, 2.659)	0.520 (0.122, 2.224) 0.378	-0.043 (-0.147 - 0.061)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.514

Table 1.26.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL												
Endocrine disorders		8.1% (3.4, 18.0)	5.9% (1.5, 20.7)	P=0.020, I <sup>2</sup> =0%	P=0.157, I <sup>2</sup> =0%	1.484 (0.262, 8.417)	1.419 (0.301, 6.685) 0.658	0.024 (-0.077 - 0.126)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.369
Endocrine disorders	Secondary hypothyroidism	6.5% (2.4, 16.0)	2.9% (0.4, 18.1)	P=0.038, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	2.424 (0.253, 23.246)	2.270 (0.271, 19.006) 0.449	0.037 (-0.045 - 0.119)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.510
Skin and subcutaneous tissue disorders		8.1% (3.4, 18.0)	2.9% (0.4, 18.1)	P=0.020, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	3.125 (0.340, 28.731)	2.838 (0.355, 22.697) 0.325	0.053 (-0.034 - 0.141)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.803
Eye disorders		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.583

Table 1.26.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL												
Musculoskeletal and connective tissue disorders		8.1% (3.4, 18.0)	8.8% (2.9, 24.0)	P=0.020, I <sup>2</sup> =0%	P=0.080, I <sup>2</sup> =0%	0.938 (0.200, 4.388)	0.946 (0.251, 3.567) 0.935	-0.005 (-0.118 - 0.109)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.737
Musculoskeletal and connective tissue disorders	Pain in extremity	6.5% (2.4, 16.0)	2.9% (0.4, 18.1)	P=0.038, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	2.424 (0.253, 23.246)	2.270 (0.271, 19.006) 0.449	0.037 (-0.045 - 0.119)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.510
Blood and lymphatic system disorders		6.5% (2.4, 16.0)	0%	P=0.038, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.066 (0.004 - 0.128)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.421

Table 1.26.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL												
Any adverse event		85.3% (78.5, 90.2)	78.7% (68.0, 86.5)	P=0.000, I <sup>2</sup> =91.6%	P=0.001, I <sup>2</sup> =88%	1.720 (0.789, 3.750)	1.088 (0.957, 1.236) 0.198	0.069 (-0.034 - 0.171)	P=0.521, I <sup>2</sup> =0%	P=0.446, I <sup>2</sup> =0%	P=0.611, I <sup>2</sup> =0%	
Infections and infestations		55.9% (47.7, 63.9)	60.0% (48.6, 70.4)	P=0.017, I <sup>2</sup> =82%	P=0.345, I <sup>2</sup> =0%	0.849 (0.478, 1.507)	0.935 (0.741, 1.179) 0.57	-0.039 (-0.175 - 0.097)	P=0.535, I <sup>2</sup> =0%	P=0.466, I <sup>2</sup> =0%	P=0.517, I <sup>2</sup> =0%	
Infections and infestations	Upper respiratory tract infection	24.5% (18.1, 32.2)	29.3% (20.2, 40.6)	P=0.000, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%	0.716 (0.331, 1.547)	0.848 (0.586, 1.229) 0.384	-0.044 (-0.147 - 0.059)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.26.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL												
Infections and infestations	Pharyngitis	4.9% (2.4, 9.9)	6.7% (2.8, 15.0)	P=0.001, I <sup>2</sup> =0%	P=0.005, I <sup>2</sup> =0%	0.689 (0.202, 2.351)	0.721 (0.246, 2.107) 0.549	-0.019 (-0.083 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Nasopharyngitis	3.5% (1.5, 8.1)	6.7% (2.8, 15.0)	P=0.006, I <sup>2</sup> =0%	P=0.005, I <sup>2</sup> =0%	0.476 (0.128, 1.771)	0.515 (0.160, 1.659) 0.266	-0.033 (-0.095 - 0.030)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Bronchitis	5.6% (2.8, 10.8)	2.7% (0.7, 10.0)	P=0.001, I <sup>2</sup> =0%	P=0.109, I <sup>2</sup> =0%	2.269 (0.458, 11.234)	2.133 (0.475, 9.573) 0.323	0.030 (-0.021 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Tonsillitis	2.8% (1.1, 7.2)	5.3% (2.0, 13.4)	P=0.022, I <sup>2</sup> =0%	P=0.022, I <sup>2</sup> =0%	0.507 (0.120, 2.146)	0.533 (0.141, 2.020) 0.355	-0.025 (-0.081 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.26.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL												
Infections and infestations	Pharyngitis streptococcal	0%	5.3% (2.0, 13.4)	P=1.000, I <sup>2</sup> =0%	P=0.012, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.054 (-0.105 - -0.003)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders		30.8% (23.8, 38.8)	20.0% (12.4, 30.6)	P=0.153, I <sup>2</sup> =50.2%	P=0.243, I <sup>2</sup> =24%	1.804 (0.919, 3.539)	1.544 (0.926, 2.576) 0.096	0.109 (-0.008 - 0.226)	P=0.811, I <sup>2</sup> =0%	P=0.727, I <sup>2</sup> =0%	P=0.980, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Cough	18.9% (13.3, 26.1)	14.7% (8.3, 24.6)	P=0.001, I <sup>2</sup> =89.8%	P=0.455, I <sup>2</sup> =0%	1.378 (0.637, 2.982)	1.298 (0.688, 2.448) 0.421	0.044 (-0.058 - 0.145)	P=0.177, I <sup>2</sup> =4518 %	P=0.199, I <sup>2</sup> =3928 %	P=0.100, I <sup>2</sup> =6302 %	



Table 1.26.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL												
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	2.1% (0.7, 6.3)	5.3% (2.0, 13.4)	P=0.047, I <sup>2</sup> =0%	P=0.022, I <sup>2</sup> =0%	0.375 (0.080, 1.766)	0.400 (0.094, 1.700) 0.215	-0.032 (-0.087 - 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations		26.6% (20.0, 34.4)	28.0% (19.0, 39.2)	P=0.000, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%	0.929 (0.431, 2.003)	0.965 (0.667, 1.397) 0.851	-0.010 (-0.112 - 0.092)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood glucose increased	9.1% (5.4, 15.0)	16.0% (9.3, 26.1)	P=0.000, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%	0.489 (0.198, 1.207)	0.578 (0.291, 1.145) 0.116	-0.067 (-0.157 - 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Insulin-like growth factor increased	15.4% (10.3, 22.3)	2.7% (0.7, 10.0)	P=0.000, I <sup>2</sup> =0%	P=0.109, I <sup>2</sup> =0%	7.887 (1.749, 35.569)	5.867 (1.453, 23.689) 0.013	0.129 (0.062 - 0.197)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.26.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL												
Investigations	Blood alkaline phosphatase increased	1.4% (0.4, 5.4)	5.3% (2.0, 13.4)	P=0.106, I <sup>2</sup> =0%	P=0.022, I <sup>2</sup> =0%	0.247 (0.043, 1.410)	0.267 (0.051, 1.393) 0.117	-0.039 (-0.093 - 0.015)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders		15.4% (10.3, 22.3)	18.7% (11.4, 29.1)	P=0.238, I <sup>2</sup> =26.8%	P=0.359, I <sup>2</sup> =0%	0.793 (0.381, 1.652)	0.823 (0.446, 1.520) 0.534	-0.033 (-0.140 - 0.074)	P=0.153, I <sup>2</sup> =5113%	P=0.154, I <sup>2</sup> =5086%	P=0.153, I <sup>2</sup> =5109%	
Gastrointestinal disorders	Diarrhoea	2.1% (0.7, 6.3)	5.3% (2.0, 13.4)	P=0.047, I <sup>2</sup> =0%	P=0.022, I <sup>2</sup> =0%	0.375 (0.080, 1.766)	0.400 (0.094, 1.700) 0.215	-0.032 (-0.087 - 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Vomiting	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.26.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL												
General disorders and administration site conditions		17.5% (12.1, 24.6)	22.7% (14.6, 33.5)	P=0.200, I <sup>2</sup> =37.3%	P=0.282, I <sup>2</sup> =11%	0.723 (0.361, 1.452)	0.774 (0.449, 1.336) 0.358	-0.051 (-0.164 - 0.062)	P=0.966, I <sup>2</sup> =0%	P=0.994, I <sup>2</sup> =0%	P=0.840, I <sup>2</sup> =0%	
General disorders and administration site conditions	Pyrexia	14.0% (9.2, 20.7)	16.0% (9.3, 26.1)	P=0.464, I <sup>2</sup> =0%	P=0.307, I <sup>2</sup> =0%	0.856 (0.392, 1.868)	0.877 (0.455, 1.692) 0.696	-0.020 (-0.120 - 0.081)	P=0.712, I <sup>2</sup> =0%	P=0.721, I <sup>2</sup> =0%	P=0.662, I <sup>2</sup> =0%	
Nervous system disorders		7.0% (3.8, 12.5)	6.7% (2.8, 15.0)	P=0.000, I <sup>2</sup> =0%	P=0.005, I <sup>2</sup> =0%	1.034 (0.324, 3.302)	1.029 (0.381, 2.779) 0.954	0.002 (-0.065 - 0.069)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.26.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL												
Nervous system disorders	Headache	6.3% (3.3, 11.7)	5.3% (2.0, 13.4)	P=0.000, I <sup>2</sup> =0%	P=0.012, I <sup>2</sup> =0%	1.182 (0.337, 4.149)	1.158 (0.384, 3.496) 0.795	0.008 (-0.054 - 0.071)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications		6.3% (3.3, 11.7)	5.3% (2.0, 13.4)	P=0.000, I <sup>2</sup> =0%	P=0.012, I <sup>2</sup> =0%	1.182 (0.337, 4.149)	1.158 (0.384, 3.496) 0.795	0.008 (-0.054 - 0.071)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders		6.3% (3.3, 11.7)	6.7% (2.8, 15.0)	P=0.000, I <sup>2</sup> =0%	P=0.010, I <sup>2</sup> =0%	0.955 (0.297, 3.068)	0.960 (0.345, 2.672) 0.938	-0.003 (-0.070 - 0.064)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.26.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL												
Endocrine disorders		2.8% (1.1, 7.2)	5.3% (2.0, 13.4)	P=0.014, I <sup>2</sup> =0%	P=0.012, I <sup>2</sup> =0%	0.484 (0.114, 2.066)	0.515 (0.137, 1.936) 0.326	-0.026 (-0.083 - 0.030)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Secondary hypothyroidism	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders		5.6% (2.8, 10.8)	1.3% (0.2, 8.9)	P=0.001, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	4.657 (0.561, 38.641)	4.267 (0.553, 32.916) 0.164	0.043 (-0.002 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders		5.6% (2.8, 10.8)	4.0% (1.3, 11.7)	P=0.001, I <sup>2</sup> =0%	P=0.049, I <sup>2</sup> =0%	1.473 (0.368, 5.891)	1.422 (0.399, 5.065) 0.587	0.017 (-0.040 - 0.074)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.26.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL												
Musculoskeletal and connective tissue disorders		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders	Pain in extremity	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.												

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Any adverse event		82.1% (73.2, 88.6)	79.4% (67.8, 87.5)	P=0.001, I <sup>2</sup> =90.7%	P=0.009, I <sup>2</sup> =85%	1.577 (0.707, 3.518)	1.060 (0.952, 1.179) 0.288	0.050 (-0.041 - 0.140)	P=0.502, I <sup>2</sup> =0%	P=0.657, I <sup>2</sup> =0%	P=0.775, I <sup>2</sup> =0%	P=0.644
Infections and infestations		58.3% (50.2, 65.9)	64.3% (53.5, 73.8)	P=0.589, I <sup>2</sup> =0%	P=0.719, I <sup>2</sup> =0%	0.777 (0.448, 1.349)	0.907 (0.736, 1.118) 0.36	-0.060 (-0.189 - 0.069)	P=0.980, I <sup>2</sup> =0%	P=0.942, I <sup>2</sup> =0%	P=0.966, I <sup>2</sup> =0%	P=0.635
Infections and infestations	Upper respiratory tract infection	41.9% (31.9, 52.5)	52.7% (38.8, 66.3)	P=0.001, I <sup>2</sup> =90.7%	P=0.001, I <sup>2</sup> =90%	0.596 (0.289, 1.227)	0.776 (0.550, 1.094) 0.148	-0.072 (-0.173 - 0.029)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.970

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Infections and infestations	Nasopharyngitis	8.5% (4.2, 16.4)	15.4% (7.6, 28.6)	P=0.045, I <sup>2</sup> =75.1%	P=0.037, I <sup>2</sup> =77%	0.492 (0.158, 1.530)	0.544 (0.207, 1.433) 0.218	-0.038 (-0.104 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.861
Infections and infestations	Pharyngitis	8.5% (4.2, 16.4)	10.6% (4.6, 22.4)	P=0.045, I <sup>2</sup> =75.1%	P=0.072, I <sup>2</sup> =69%	0.734 (0.216, 2.500)	0.762 (0.260, 2.233) 0.62	-0.014 (-0.073 - 0.044)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.553
Infections and infestations	Pharyngitis streptococcal	2.1% (0.6, 7.1)	8.3% (3.3, 19.2)	P=0.308, I <sup>2</sup> =3.9%	P=0.107, I <sup>2</sup> =61%	0.250 (0.044, 1.436)	0.272 (0.052, 1.416) 0.122	-0.035 (-0.084 - 0.014)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.809
Infections and infestations	Gastroenteritis	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.845



Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Infections and infestations	Viral infection	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.660
Infections and infestations	Croup infectious	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.644
Infections and infestations	Ear infection	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.644

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Infections and infestations	Conjunctivitis	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.620
Infections and infestations	Gastroenteritis viral	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.620
Infections and infestations	Bronchitis	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
Infections and infestations	Enterobiasis	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Infections and infestations	Laryngitis viral	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
Infections and infestations	Pneumonia	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
Infections and infestations	Respiratory tract infection	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
Infections and infestations	Respiratory tract infection viral	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Investigations		45.4% (35.2, 56.0)	48.7% (35.1, 62.5)	P=0.001, I <sup>2</sup> =91.2%	P=0.002, I <sup>2</sup> =89%	0.819 (0.400, 1.676)	0.906 (0.639, 1.284) 0.579	-0.028 (-0.128 - 0.072)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.816
Investigations	Blood glucose increased	15.0% (9.2, 23.7)	26.4% (16.3, 39.8)	P=0.022, I <sup>2</sup> =81%	P=0.018, I <sup>2</sup> =82%	0.478 (0.205, 1.118)	0.566 (0.296, 1.083) 0.086	-0.072 (-0.159 - 0.015)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.318
Investigations	Insulin-like growth factor increased	27.8% (19.5, 37.9)	5.1% (1.8, 13.6)	P=0.005, I <sup>2</sup> =87.5%	P=0.290, I <sup>2</sup> =11%	6.322 (1.793, 22.288)	4.719 (1.505, 14.797) 0.008	0.132 (0.063 - 0.201)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.544
Investigations	Blood glucose abnormal	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.600

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Investigations	Blood iron decreased	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.644
Investigations	Thyroxine decreased	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.644
Investigations	Liver function test abnormal	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.620

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Investigations	Thyroid function test abnormal	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.620
Investigations	Alanine aminotransferase increased	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
Investigations	Aspartate aminotransferase increased	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
Investigations	Thyroxine free decreased	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Respiratory, thoracic and mediastinal disorders		31.3% (24.4, 39.2)	21.8% (14.2, 32.0)	P=0.265, I <sup>2</sup> =19.6%	P=0.305, I <sup>2</sup> =5%	1.673 (0.893, 3.137)	1.457 (0.910, 2.335) 0.117	0.098 (-0.016 - 0.212)	P=0.795, I <sup>2</sup> =0%	P=0.731, I <sup>2</sup> =0%	P=0.941, I <sup>2</sup> =0%	P=0.567
Respiratory, thoracic and mediastinal disorders	Cough	25.5% (17.5, 35.4)	14.5% (7.5, 26.1)	P=0.006, I <sup>2</sup> =86.8%	P=0.064, I <sup>2</sup> =71%	1.869 (0.760, 4.596)	1.628 (0.792, 3.346) 0.185	0.059 (-0.021 - 0.139)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.330
Respiratory, thoracic and mediastinal disorders	Nasal congestion	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.620
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
Respiratory, thoracic and mediastinal disorders	Wheezing	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
General disorders and administration site conditions		18.6% (13.2, 25.7)	22.8% (15.0, 33.0)	P=0.499, I <sup>2</sup> =0%	P=0.473, I <sup>2</sup> =0%	0.780 (0.405, 1.505)	0.822 (0.490, 1.378) 0.457	-0.040 (-0.149 - 0.068)	P=0.889, I <sup>2</sup> =0%	P=0.907, I <sup>2</sup> =0%	P=0.833, I <sup>2</sup> =0%	P=0.308



Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
General disorders and administration site conditions	Pyrexia	15.9% (10.9, 22.6)	14.3% (8.3, 23.5)	P=0.932, I <sup>2</sup> =0%	P=0.858, I <sup>2</sup> =0%	1.134 (0.535, 2.403)	1.113 (0.587, 2.110) 0.744	0.016 (-0.079 - 0.111)	P=0.845, I <sup>2</sup> =0%	P=0.844, I <sup>2</sup> =0%	P=0.845, I <sup>2</sup> =0%	P=0.617
General disorders and administration site conditions	Face oedema	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
General disorders and administration site conditions	Fatigue	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
General disorders and administration site conditions	Influenza like illness	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
Gastrointestinal disorders		22.1% (16.2, 29.5)	17.9% (11.1, 27.6)	P=0.216, I <sup>2</sup> =34.6%	P=0.728, I <sup>2</sup> =0%	1.282 (0.651, 2.525)	1.222 (0.704, 2.119) 0.476	0.040 (-0.066 - 0.145)	P=0.324, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	P=0.293, I <sup>2</sup> =957%	P=0.421
Gastrointestinal disorders	Vomiting	8.5% (4.2, 16.4)	6.0% (2.1, 15.9)	P=0.045, I <sup>2</sup> =75.1%	P=0.168, I <sup>2</sup> =47%	1.301 (0.316, 5.359)	1.270 (0.349, 4.621) 0.717	0.010 (-0.041 - 0.060)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.524

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Gastrointestinal disorders	Abdominal pain	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.620
Gastrointestinal disorders	Toothache	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.620
Gastrointestinal disorders	Diarrhoea	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Nervous system disorders		12.5% (6.9, 21.6)	17.8% (9.3, 31.6)	P=0.021, I <sup>2</sup> =81.1%	P=0.027, I <sup>2</sup> =80%	0.625 (0.223, 1.752)	0.680 (0.294, 1.574) 0.368	-0.031 (-0.101 - 0.040)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.806
Nervous system disorders	Headache	11.2% (6.0, 19.9)	13.0% (6.1, 25.6)	P=0.027, I <sup>2</sup> =79.6%	P=0.051, I <sup>2</sup> =74%	0.788 (0.257, 2.417)	0.816 (0.315, 2.115) 0.676	-0.013 (-0.077 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.925
Metabolism and nutrition disorders		10.5% (5.8, 18.2)	14.5% (7.5, 26.1)	P=0.044, I <sup>2</sup> =75.2%	P=0.064, I <sup>2</sup> =71%	0.668 (0.244, 1.829)	0.708 (0.300, 1.670) 0.43	-0.028 (-0.099 - 0.044)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.756
Metabolism and nutrition disorders	Hyperuricaemia	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Injury, poisoning and procedural complications		13.9% (7.9, 23.3)	6.0% (2.1, 15.9)	P=0.017, I <sup>2</sup> =82.4%	P=0.168, I <sup>2</sup> =47%	2.187 (0.570, 8.398)	1.995 (0.594, 6.705) 0.264	0.036 (-0.019 - 0.091)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.792
Injury, poisoning and procedural complications	Animal bite	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
Injury, poisoning and procedural complications	Burns first degree	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Injury, poisoning and procedural complications	Concussion	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
Musculoskeletal and connective tissue disorders		9.8% (5.1, 18.2)	13.0% (6.1, 25.6)	P=0.034, I <sup>2</sup> =77.6%	P=0.051, I <sup>2</sup> =74%	0.689 (0.219, 2.162)	0.725 (0.272, 1.933) 0.521	-0.020 (-0.083 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.747
Musculoskeletal and connective tissue disorders	Pain in extremity	3.3% (1.2, 9.0)	8.3% (3.3, 19.2)	P=0.184, I <sup>2</sup> =43.4%	P=0.107, I <sup>2</sup> =61%	0.381 (0.080, 1.802)	0.408 (0.096, 1.727) 0.223	-0.028 (-0.078 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.974

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Skin and subcutaneous tissue disorders		8.5% (4.2, 16.4)	3.9% (1.1, 12.5)	P=0.045, I <sup>2</sup> =75.1%	P=0.289, I <sup>2</sup> =11%	2.008 (0.395, 10.204)	1.904 (0.417, 8.704) 0.406	0.022 (-0.024 - 0.067)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.379
Skin and subcutaneous tissue disorders	Rash pruritic	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.644
Skin and subcutaneous tissue disorders	Rash	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.620
Skin and subcutaneous tissue disorders	Urticaria	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Eye disorders		0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Eye disorders	Refraction disorder	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.845
Eye disorders	Myopia	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.644
Eye disorders	Strabismus	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.644



Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Eye disorders	Vernal keratoconjunctivitis	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.620
Eye disorders	Papilloedema	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
Blood and lymphatic system disorders		0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.660

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Blood and lymphatic system disorders	Anaemia	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
Blood and lymphatic system disorders	Iron deficiency anaemia	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
Blood and lymphatic system disorders	Hypochromic anaemia	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
Endocrine disorders		0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.845

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Endocrine disorders	Precocious puberty	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.620
Endocrine disorders	Diabetes insipidus	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
Endocrine disorders	Hypothyroidis m	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
Endocrine disorders	Secondary adrenocortical insufficiency	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Endocrine disorders	Secondary hypothyroidism	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
Reproductive system and breast disorders		0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.674
Hepatobiliary disorders		0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.644
Hepatobiliary disorders	Hepatomegaly	0.7% (0.1, 4.5)	1.2% (0.2, 7.8)	P=0.921, I <sup>2</sup> =0%	P=0.906, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.644

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Any adverse event		83.1% (63.8, 93.2)	55.6% (27.4, 80.6)	P=0.185, I <sup>2</sup> =43%	P=0.106, I <sup>2</sup> =62%	4.688 (0.843, 26.076)	1.329 (0.913, 1.936) 0.138	0.215 (-0.041 - 0.472)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations		60.1% (42.5, 75.4)	41.2% (16.3, 71.5)	P=0.279, I <sup>2</sup> =14.7%	P=0.055, I <sup>2</sup> =73%	2.038 (0.533, 7.798)	1.358 (0.731, 2.523) 0.333	0.157 (-0.137 - 0.452)	P=0.243, I <sup>2</sup> =2658%	P=0.086, I <sup>2</sup> =6607%	P=0.164, I <sup>2</sup> =4831%	
Infections and infestations	Upper respiratory tract infection	35.1% (17.6, 57.8)	34.3% (11.8, 66.9)	P=0.013, I <sup>2</sup> =83.9%	P=0.076, I <sup>2</sup> =68%	0.585 (0.108, 3.173)	0.749 (0.313, 1.789) 0.515	-0.074 (-0.313 - 0.164)	P=0.823, I <sup>2</sup> =0%	P=0.680, I <sup>2</sup> =0%	P=0.867, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Infections and infestations	Nasopharyngitis	20.8% (9.5, 39.5)	24.5% (6.7, 59.6)	P=0.186, I <sup>2</sup> =42.8%	P=0.139, I <sup>2</sup> =54%	1.290 (0.258, 6.451)	1.269 (0.290, 5.563) 0.752	0.041 (-0.205 - 0.286)	P=0.038, I <sup>2</sup> =7678%	P=0.041, I <sup>2</sup> =7613%	P=0.027, I <sup>2</sup> =7957%	
Infections and infestations	Pharyngitis	12.5% (4.4, 30.7)	6.4% (0.9, 34.4)	P=0.281, I <sup>2</sup> =14%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.098 (-0.003 - 0.200)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pharyngitis streptococcal	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Gastroenteritis	5.0% (1.0, 21.5)	12.3% (2.4, 44.3)	P=0.535, I <sup>2</sup> =0%	P=0.395, I <sup>2</sup> =0%	0.308 (0.015, 6.117)	0.357 (0.027, 4.699) 0.434	-0.048 (-0.193 - 0.096)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Infections and infestations	Viral infection	8.3% (2.4, 25.0)	6.4% (0.9, 34.4)	P=0.449, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.066 (-0.019 - 0.150)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Croup infectious	2.9% (0.4, 17.8)	10.1% (2.0, 37.8)	P=0.884, I <sup>2</sup> =0%	P=0.861, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.069 (-0.203 - 0.064)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Ear infection	2.9% (0.4, 17.8)	10.1% (2.0, 37.8)	P=0.884, I <sup>2</sup> =0%	P=0.861, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.069 (-0.203 - 0.064)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Infections and infestations	Conjunctivitis	2.9% (0.4, 17.8)	12.3% (2.4, 44.3)	P=0.884, I <sup>2</sup> =0%	P=0.395, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.075 (-0.213 - 0.063)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Gastroenteritis viral	2.9% (0.4, 17.8)	12.3% (2.4, 44.3)	P=0.884, I <sup>2</sup> =0%	P=0.395, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.075 (-0.213 - 0.063)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Bronchitis	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Enterobiasis	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Infections and infestations	Laryngitis viral	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pneumonia	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Respiratory tract infection	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Respiratory tract infection viral	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Investigations		44.9% (23.8, 68.1)	34.3% (11.8, 66.9)	P=0.003, I <sup>2</sup> =88.7%	P=0.076, I <sup>2</sup> =68%	0.861 (0.157, 4.719)	0.931 (0.417, 2.079) 0.862	-0.020 (-0.252 - 0.212)	P=0.586, I <sup>2</sup> =0%	P=0.547, I <sup>2</sup> =0%	P=0.681, I <sup>2</sup> =0%	
Investigations	Blood glucose increased	9.9% (2.9, 29.2)	36.7% (11.3, 72.5)	P=0.249, I <sup>2</sup> =24.8%	P=0.051, I <sup>2</sup> =74%	0.111 (0.011, 1.145)	0.238 (0.055, 1.035) 0.056	-0.172 (-0.385 - 0.041)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Insulin-like growth factor increased	21.1% (8.4, 43.9)	6.4% (0.9, 34.4)	P=0.076, I <sup>2</sup> =68.2%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.108 (0.001 - 0.214)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood glucose abnormal	5.0% (1.0, 21.5)	24.5% (6.7, 59.6)	P=0.535, I <sup>2</sup> =0%	P=0.139, I <sup>2</sup> =54%	0.115 (0.008, 1.732)	0.179 (0.020, 1.568) 0.12	-0.124 (-0.311 - 0.064)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Investigations	Blood iron decreased	2.9% (0.4, 17.8)	10.1% (2.0, 37.8)	P=0.884, I <sup>2</sup> =0%	P=0.861, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.069 (-0.203 - 0.064)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Thyroxine decreased	2.9% (0.4, 17.8)	10.1% (2.0, 37.8)	P=0.884, I <sup>2</sup> =0%	P=0.861, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.069 (-0.203 - 0.064)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Liver function test abnormal	2.9% (0.4, 17.8)	12.3% (2.4, 44.3)	P=0.884, I <sup>2</sup> =0%	P=0.395, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.075 (-0.213 - 0.063)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Investigations	Thyroid function test abnormal	2.9% (0.4, 17.8)	12.3% (2.4, 44.3)	P=0.884, I <sup>2</sup> =0%	P=0.395, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.075 (-0.213 - 0.063)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Alanine aminotransferase increased	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Aspartate aminotransferase increased	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Thyroxine free decreased	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Respiratory, thoracic and mediastinal disorders		30.3% (17.2, 47.8)	12.3% (2.4, 44.3)	P=0.853, I <sup>2</sup> =0%	P=0.395, I <sup>2</sup> =0%	5.264 (0.620, 44.679)	4.046 (0.604, 27.092) 0.15	0.229 (0.018 - 0.441)	P=0.313, I <sup>2</sup> =171%	P=0.269, I <sup>2</sup> =1801%	P=0.448, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Cough	27.3% (14.8, 44.7)	6.4% (0.9, 34.4)	P=0.886, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.272 (0.119 - 0.424)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.610, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Nasal congestion	2.9% (0.4, 17.8)	12.3% (2.4, 44.3)	P=0.884, I <sup>2</sup> =0%	P=0.395, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.075 (-0.213 - 0.063)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Wheezing	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions		27.6% (15.0, 45.2)	12.3% (2.4, 44.3)	P=0.520, I <sup>2</sup> =0%	P=0.395, I <sup>2</sup> =0%	4.422 (0.540, 36.197)	3.689 (0.540, 25.217) 0.183	0.202 (-0.009 - 0.414)	P=0.237, I <sup>2</sup> =2839 %	P=0.206, I <sup>2</sup> =3748 %	P=0.286, I <sup>2</sup> =1221 %	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
General disorders and administration site conditions	Pyrexia	21.2% (10.5, 38.3)	12.3% (2.4, 44.3)	P=0.979, I <sup>2</sup> =0%	P=0.395, I <sup>2</sup> =0%	3.312 (0.372, 29.482)	2.816 (0.407, 19.498) 0.294	0.137 (-0.060 - 0.334)	P=0.358, I <sup>2</sup> =0%	P=0.321, I <sup>2</sup> =0%	P=0.503, I <sup>2</sup> =0%	
General disorders and administration site conditions	Face oedema	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
General disorders and administration site conditions	Fatigue	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Influenza like illness	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders		15.2% (6.5, 31.7)	24.5% (6.7, 59.6)	P=0.905, I <sup>2</sup> =0%	P=0.139, I <sup>2</sup> =54%	1.013 (0.178, 5.774)	1.011 (0.235, 4.357) 0.988	0.002 (-0.224 - 0.227)	P=0.142, I <sup>2</sup> =5371%	P=0.137, I <sup>2</sup> =5473%	P=0.117, I <sup>2</sup> =5919%	
Gastrointestinal disorders	Vomiting	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Gastrointestinal disorders	Abdominal pain	2.9% (0.4, 17.8)	12.3% (2.4, 44.3)	P=0.884, I <sup>2</sup> =0%	P=0.395, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.075 (-0.213 - 0.063)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Toothache	2.9% (0.4, 17.8)	12.3% (2.4, 44.3)	P=0.884, I <sup>2</sup> =0%	P=0.395, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.075 (-0.213 - 0.063)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Diarrhoea	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Nervous system disorders		16.9% (6.8, 36.2)	12.3% (2.4, 44.3)	P=0.185, I <sup>2</sup> =43%	P=0.395, I <sup>2</sup> =0%	1.745 (0.211, 14.428)	1.745 (0.218, 13.959) 0.6	0.056 (-0.135 - 0.247)	P=0.071, I <sup>2</sup> =6926%	P=0.076, I <sup>2</sup> =6826%	P=0.070, I <sup>2</sup> =6949%	
Nervous system disorders	Headache	16.9% (6.8, 36.2)	12.3% (2.4, 44.3)	P=0.185, I <sup>2</sup> =43%	P=0.395, I <sup>2</sup> =0%	1.745 (0.211, 14.428)	1.745 (0.218, 13.959) 0.6	0.056 (-0.135 - 0.247)	P=0.071, I <sup>2</sup> =6926%	P=0.076, I <sup>2</sup> =6826%	P=0.070, I <sup>2</sup> =6949%	
Metabolism and nutrition disorders		2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Hyperuricaemia	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Injury, poisoning and procedural complications		8.3% (2.4, 25.0)	6.4% (0.9, 34.4)	P=0.449, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.066 (-0.019 - 0.150)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Animal bite	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Burns first degree	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Injury, poisoning and procedural complications	Concussion	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders		2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders	Pain in extremity	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Skin and subcutaneous tissue disorders		10.1% (3.3, 27.3)	14.8% (3.7, 44.0)	P=0.391, I <sup>2</sup> =0%	P=0.653, I <sup>2</sup> =0%	0.555 (0.079, 3.880)	0.599 (0.112, 3.199) 0.549	-0.058 (-0.264 - 0.148)	P=0.840, I <sup>2</sup> =0%	P=0.814, I <sup>2</sup> =0%	P=0.995, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Rash pruritic	2.9% (0.4, 17.8)	10.1% (2.0, 37.8)	P=0.884, I <sup>2</sup> =0%	P=0.861, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.069 (-0.203 - 0.064)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Rash	2.9% (0.4, 17.8)	12.3% (2.4, 44.3)	P=0.884, I <sup>2</sup> =0%	P=0.395, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.075 (-0.213 - 0.063)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Urticaria	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatropin in Mean (95%CI)	Daily somatropin in Mean (95%CI)	Lonapeg somatropin in	Daily somatropin in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Eye disorders		10.1% (3.3, 27.3)	29.2% (11.3, 57.4)	P=0.391, I <sup>2</sup> =0%	P=0.486, I <sup>2</sup> =0%	0.222 (0.040, 1.238)	0.299 (0.077, 1.162) 0.081	-0.203 (-0.456 - 0.050)	P=0.887, I <sup>2</sup> =0%	P=0.772, I <sup>2</sup> =0%	P=0.749, I <sup>2</sup> =0%	
Eye disorders	Refraction disorder	5.0% (1.0, 21.5)	12.3% (2.4, 44.3)	P=0.535, I <sup>2</sup> =0%	P=0.395, I <sup>2</sup> =0%	0.308 (0.015, 6.117)	0.357 (0.027, 4.699) 0.434	-0.048 (-0.193 - 0.096)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Myopia	2.9% (0.4, 17.8)	10.1% (2.0, 37.8)	P=0.884, I <sup>2</sup> =0%	P=0.861, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.069 (-0.203 - 0.064)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Strabismus	2.9% (0.4, 17.8)	10.1% (2.0, 37.8)	P=0.884, I <sup>2</sup> =0%	P=0.861, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.069 (-0.203 - 0.064)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Eye disorders	Vernal keratoconjunctivitis	2.9% (0.4, 17.8)	12.3% (2.4, 44.3)	P=0.884, I <sup>2</sup> =0%	P=0.395, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.075 (-0.213 - 0.063)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Papilloedema	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders		8.3% (2.4, 25.0)	6.4% (0.9, 34.4)	P=0.449, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.066 (-0.019 - 0.150)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Blood and lymphatic system disorders	Anaemia	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Iron deficiency anaemia	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Hypochromic anaemia	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders		5.0% (1.0, 21.5)	12.3% (2.4, 44.3)	P=0.535, I <sup>2</sup> =0%	P=0.395, I <sup>2</sup> =0%	0.308 (0.015, 6.117)	0.357 (0.027, 4.699) 0.434	-0.048 (-0.193 - 0.096)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Endocrine disorders	Precocious puberty	2.9% (0.4, 17.8)	12.3% (2.4, 44.3)	P=0.884, I <sup>2</sup> =0%	P=0.395, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.075 (-0.213 - 0.063)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Diabetes insipidus	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Hypothyroidism	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Secondary adrenocortical insufficiency	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Endocrine disorders	Secondary hypothyroidism	2.9% (0.4, 17.8)	6.4% (0.9, 34.4)	P=0.884, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Reproductive system and breast disorders		9.9% (2.9, 29.2)	6.4% (0.9, 34.4)	P=0.249, I <sup>2</sup> =24.8%	P=0.792, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.054 (-0.024 - 0.131)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Hepatobiliary disorders		2.9% (0.4, 17.8)	10.1% (2.0, 37.8)	P=0.884, I <sup>2</sup> =0%	P=0.861, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.069 (-0.203 - 0.064)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Hepatobiliary disorders	Hepatomegaly	2.9% (0.4, 17.8)	10.1% (2.0, 37.8)	P=0.884, I <sup>2</sup> =0%	P=0.861, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.069 (-0.203 - 0.064)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Any adverse event		79.2% (57.4, 91.5)	86.7% (53.5, 97.4)	P=0.668, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	0.389 (0.037, 4.061)	0.880 (0.663, 1.167) 0.374	-0.109 (-0.348 - 0.129)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations		40.7% (22.0, 62.5)	63.5% (33.3, 85.8)	P=0.277, I <sup>2</sup> =15.4%	P=0.272, I <sup>2</sup> =17%	0.343 (0.066, 1.770)	0.635 (0.329, 1.225) 0.175	-0.229 (-0.564 - 0.106)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Upper respiratory tract infection	5.6% (0.8, 31.3)	13.3% (2.6, 46.5)	P=0.424, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Infections and infestations	Nasopharyngitis	5.6% (0.8, 31.3)	13.3% (2.6, 46.5)	P=0.424, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pharyngitis	5.6% (0.8, 31.3)	46.4% (21.4, 73.4)	P=0.424, I <sup>2</sup> =0%	P=0.530, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.448 (-0.744 - -0.152)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pharyngitis streptococcal	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Gastroenteritis	5.6% (0.8, 31.3)	20.9% (6.1, 51.6)	P=0.424, I <sup>2</sup> =0%	P=0.874, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.179 (-0.406 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Infections and infestations	Viral infection	11.4% (3.3, 32.4)	10.1% (1.3, 48.4)	P=0.937, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.100 (-0.029 - 0.228)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Croup infectious	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Ear infection	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Infections and infestations	Conjunctivitis	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Gastroenteritis viral	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Bronchitis	7.2% (1.4, 29.2)	20.9% (6.1, 51.6)	P=0.628, I <sup>2</sup> =0%	P=0.874, I <sup>2</sup> =0%	0.235 (0.018, 2.993)	0.278 (0.029, 2.696) 0.269	-0.129 (-0.374 - 0.115)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Enterobiasis	7.2% (1.4, 29.2)	13.3% (2.6, 46.5)	P=0.628, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	0.529 (0.030, 9.499)	0.556 (0.039, 7.957) 0.665	-0.040 (-0.232 - 0.153)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Infections and infestations	Laryngitis viral	5.6% (0.8, 31.3)	13.3% (2.6, 46.5)	P=0.424, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pneumonia	5.6% (0.8, 31.3)	20.9% (6.1, 51.6)	P=0.424, I <sup>2</sup> =0%	P=0.874, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.179 (-0.406 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Respiratory tract infection	20.8% (8.5, 42.6)	20.9% (6.1, 51.6)	P=0.668, I <sup>2</sup> =0%	P=0.874, I <sup>2</sup> =0%	1.143 (0.170, 7.693)	1.111 (0.245, 5.035) 0.891	0.020 (-0.261 - 0.300)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Respiratory tract infection viral	7.2% (1.4, 29.2)	13.3% (2.6, 46.5)	P=0.628, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	0.529 (0.030, 9.499)	0.556 (0.039, 7.957) 0.665	-0.040 (-0.232 - 0.153)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Investigations		12.5% (3.0, 40.0)	22.7% (4.9, 62.4)	P=0.181, I <sup>2</sup> =44.1%	P=0.090, I <sup>2</sup> =65%	0.290 (0.024, 3.568)	0.436 (0.090, 2.113) 0.303	-0.109 (-0.346 - 0.127)	P=0.652, I <sup>2</sup> =0%	P=0.800, I <sup>2</sup> =0%	P=0.366, I <sup>2</sup> =0%	
Investigations	Blood glucose increased	12.7% (2.3, 47.5)	22.8% (3.4, 71.1)	P=0.122, I <sup>2</sup> =58.3%	P=0.058, I <sup>2</sup> =72%	NA (NA, NA)	0.333 (0.067, 1.652) 0.178	-0.070 (-0.217 - 0.078)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Insulin-like growth factor increased	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood glucose abnormal	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Investigations	Blood iron decreased	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Thyroxine decreased	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Liver function test abnormal	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Investigations	Thyroid function test abnormal	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Alanine aminotransferase increased	5.6% (0.8, 31.3)	13.3% (2.6, 46.5)	P=0.424, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Aspartate aminotransferase increased	5.6% (0.8, 31.3)	13.3% (2.6, 46.5)	P=0.424, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Thyroxine free decreased	12.7% (2.3, 47.5)	10.1% (1.3, 48.4)	P=0.122, I <sup>2</sup> =58.3%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.035 (-0.044 - 0.114)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Respiratory, thoracic and mediastinal disorders		16.0% (5.7, 37.4)	20.9% (6.1, 51.6)	P=0.837, I <sup>2</sup> =0%	P=0.874, I <sup>2</sup> =0%	0.800 (0.110, 5.819)	0.833 (0.166, 4.184) 0.825	-0.030 (-0.301 - 0.241)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Cough	7.2% (1.4, 29.2)	13.3% (2.6, 46.5)	P=0.628, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	0.529 (0.030, 9.499)	0.556 (0.039, 7.957) 0.665	-0.040 (-0.232 - 0.153)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Nasal congestion	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	7.2% (1.4, 29.2)	13.3% (2.6, 46.5)	P=0.628, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	0.529 (0.030, 9.499)	0.556 (0.039, 7.957) 0.665	-0.040 (-0.232 - 0.153)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	5.6% (0.8, 31.3)	13.3% (2.6, 46.5)	P=0.424, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Wheezing	5.6% (0.8, 31.3)	13.3% (2.6, 46.5)	P=0.424, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions		7.2% (1.4, 29.2)	20.9% (6.1, 51.6)	P=0.628, I <sup>2</sup> =0%	P=0.874, I <sup>2</sup> =0%	0.235 (0.018, 2.993)	0.278 (0.029, 2.696) 0.269	-0.129 (-0.374 - 0.115)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
General disorders and administration site conditions	Pyrexia	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Face oedema	5.6% (0.8, 31.3)	13.3% (2.6, 46.5)	P=0.424, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
General disorders and administration site conditions	Fatigue	5.6% (0.8, 31.3)	13.3% (2.6, 46.5)	P=0.424, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Influenza like illness	5.6% (0.8, 31.3)	13.3% (2.6, 46.5)	P=0.424, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders		16.0% (5.7, 37.4)	28.6% (9.0, 61.8)	P=0.837, I <sup>2</sup> =0%	P=0.171, I <sup>2</sup> =47%	0.471 (0.087, 2.545)	0.526 (0.129, 2.145) 0.371	-0.134 (-0.452 - 0.183)	P=0.248, I <sup>2</sup> =2505%	P=0.317, I <sup>2</sup> =14%	P=0.120, I <sup>2</sup> =5865%	
Gastrointestinal disorders	Vomiting	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Gastrointestinal disorders	Abdominal pain	5.6% (0.8, 31.3)	13.3% (2.6, 46.5)	P=0.424, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Toothache	5.6% (0.8, 31.3)	13.3% (2.6, 46.5)	P=0.424, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Diarrhoea	5.6% (0.8, 31.3)	22.8% (3.4, 71.1)	P=0.424, I <sup>2</sup> =0%	P=0.058, I <sup>2</sup> =72%	NA (NA, NA)	NA (NA, NA) NA	-0.104 (-0.284 - 0.075)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Nervous system disorders		5.6% (0.8, 31.3)	22.7% (4.9, 62.4)	P=0.424, I <sup>2</sup> =0%	P=0.090, I <sup>2</sup> =65%	NA (NA, NA)	NA (NA, NA) NA	-0.194 (-0.426 - 0.038)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.145 , I <sup>2</sup> =5281 %	
Nervous system disorders	Headache	5.6% (0.8, 31.3)	22.7% (4.9, 62.4)	P=0.424, I <sup>2</sup> =0%	P=0.090, I <sup>2</sup> =65%	NA (NA, NA)	NA (NA, NA) NA	-0.194 (-0.426 - 0.038)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.145 , I <sup>2</sup> =5281 %	
Metabolism and nutrition disorders		12.7% (2.3, 47.5)	10.1% (1.3, 48.4)	P=0.122, I <sup>2</sup> =58.3%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.035 (-0.044 - 0.114)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Hyperuricaemia	12.7% (2.3, 47.5)	10.1% (1.3, 48.4)	P=0.122, I <sup>2</sup> =58.3%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.035 (-0.044 - 0.114)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	



Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Injury, poisoning and procedural complications		7.2% (1.4, 29.2)	29.2% (10.6, 58.9)	P=0.628, I <sup>2</sup> =0%	P=0.887, I <sup>2</sup> =0%	0.137 (0.012, 1.556)	0.185 (0.022, 1.554) 0.12	-0.219 (-0.497 - 0.059)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Animal bite	5.6% (0.8, 31.3)	13.3% (2.6, 46.5)	P=0.424, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Burns first degree	5.6% (0.8, 31.3)	13.3% (2.6, 46.5)	P=0.424, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Injury, poisoning and procedural complications	Concussion	5.6% (0.8, 31.3)	13.3% (2.6, 46.5)	P=0.424, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders		5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders	Pain in extremity	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Skin and subcutaneous tissue disorders		7.2% (1.4, 29.2)	13.3% (2.6, 46.5)	P=0.628, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	0.529 (0.030, 9.499)	0.556 (0.039, 7.957) 0.665	-0.040 (-0.232 - 0.153)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Rash pruritic	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Rash	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Urticaria	5.6% (0.8, 31.3)	13.3% (2.6, 46.5)	P=0.424, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Eye disorders		12.7% (2.3, 47.5)	22.8% (3.4, 71.1)	P=0.122, I <sup>2</sup> =58.3%	P=0.058, I <sup>2</sup> =72%	NA (NA, NA)	0.333 (0.067, 1.652) 0.178	-0.070 (-0.217 - 0.078)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Refraction disorder	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Myopia	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Strabismus	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Eye disorders	Vernal keratoconjunctivitis	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Papilloedema	12.7% (2.3, 47.5)	22.8% (3.4, 71.1)	P=0.122, I <sup>2</sup> =58.3%	P=0.058, I <sup>2</sup> =72%	NA (NA, NA)	0.333 (0.067, 1.652) 0.178	-0.070 (-0.217 - 0.078)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders		15.4% (5.0, 39.0)	22.7% (4.9, 62.4)	P=0.334, I <sup>2</sup> =0%	P=0.090, I <sup>2</sup> =65%	0.600 (0.073, 4.940)	0.692 (0.161, 2.972) 0.621	-0.060 (-0.316 - 0.197)	P=0.455, I <sup>2</sup> =0%	P=0.555, I <sup>2</sup> =0%	P=0.318, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Blood and lymphatic system disorders	Anaemia	5.6% (0.8, 31.3)	22.7% (4.9, 62.4)	P=0.424, I <sup>2</sup> =0%	P=0.090, I <sup>2</sup> =65%	NA (NA, NA)	NA (NA, NA) NA	-0.194 (-0.426 - 0.038)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.145 , I <sup>2</sup> =5281 %	
Blood and lymphatic system disorders	Iron deficiency anaemia	11.4% (3.3, 32.4)	10.1% (1.3, 48.4)	P=0.937, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.100 (-0.029 - 0.228)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Hypochromic anaemia	12.7% (2.3, 47.5)	10.1% (1.3, 48.4)	P=0.122, I <sup>2</sup> =58.3%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.035 (-0.044 - 0.114)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Endocrine disorders		30.6% (14.8, 52.8)	29.2% (10.6, 58.9)	P=0.431, I <sup>2</sup> =0%	P=0.887, I <sup>2</sup> =0%	1.167 (0.220, 6.199)	1.111 (0.352, 3.510) 0.858	0.030 (-0.290 - 0.350)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Endocrine disorders	Precocious puberty	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Diabetes insipidus	7.2% (1.4, 29.2)	13.3% (2.6, 46.5)	P=0.628, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	0.529 (0.030, 9.499)	0.556 (0.039, 7.957) 0.665	-0.040 (-0.232 - 0.153)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Hypothyroidism	5.6% (0.8, 31.3)	13.3% (2.6, 46.5)	P=0.424, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Secondary adrenocortical insufficiency	7.2% (1.4, 29.2)	13.3% (2.6, 46.5)	P=0.628, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	0.529 (0.030, 9.499)	0.556 (0.039, 7.957) 0.665	-0.040 (-0.232 - 0.153)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Endocrine disorders	Secondary hypothyroidism	25.7% (11.5, 47.8)	10.1% (1.3, 48.4)	P=0.536, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.249 (0.064 - 0.434)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.27.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Reproductive system and breast disorders		5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Hepatobiliary disorders		5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Hepatobiliary disorders	Hepatomegal y	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)	P=0.424, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.												

Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL												
Any adverse event		83.4% (75.1, 89.4)	79.6% (67.7, 87.9)	P=0.004, I <sup>2</sup> =87.9%	P=0.019, I <sup>2</sup> =82%	1.450 (0.646, 3.253)	1.050 (0.940, 1.173) 0.388	0.042 (-0.052 - 0.135)	P=0.766, I <sup>2</sup> =0%	P=0.555, I <sup>2</sup> =0%	P=0.645, I <sup>2</sup> =0%	P=0.491
Infections and infestations		58.4% (50.3, 66.1)	58.2% (47.1, 68.5)	P=0.247, I <sup>2</sup> =25.4%	P=0.690, I <sup>2</sup> =0%	1.011 (0.580, 1.762)	1.004 (0.798, 1.265) 0.97	0.003 (-0.132 - 0.137)	P=0.714, I <sup>2</sup> =0%	P=0.717, I <sup>2</sup> =0%	P=0.715, I <sup>2</sup> =0%	P=0.113
Infections and infestations	Upper respiratory tract infection	41.8% (31.2, 53.3)	47.0% (32.3, 62.3)	P=0.001, I <sup>2</sup> =91.1%	P=0.002, I <sup>2</sup> =90%	0.738 (0.335, 1.627)	0.856 (0.576, 1.273) 0.443	-0.036 (-0.132 - 0.060)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.489

Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE ≥ 10% in any treatment group

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL												
Infections and infestations	Nasopharyngitis	11.4% (6.3, 19.7)	9.9% (4.3, 21.0)	P=0.035, I <sup>2</sup> =77.5%	P=0.114, I <sup>2</sup> =60%	1.091 (0.346, 3.438)	1.079 (0.395, 2.945) 0.882	0.005 (-0.060 - 0.070)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.160
Infections and infestations	Pharyngitis	8.9% (4.6, 16.6)	16.4% (8.6, 29.3)	P=0.054, I <sup>2</sup> =73%	P=0.048, I <sup>2</sup> =75%	0.485 (0.167, 1.407)	0.539 (0.219, 1.331) 0.181	-0.047 (-0.120 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.970
Infections and infestations	Pharyngitis streptococcal	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.431
Infections and infestations	Tonsillitis	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.979

Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL												
Infections and infestations	Respiratory tract infection	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.750
Infections and infestations	Gastroenteritis	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.578
Respiratory, thoracic and mediastinal disorders		28.7% (22.0, 36.6)	14.5% (8.2, 24.4)	P=0.322, I <sup>2</sup> =0%	P=0.273, I <sup>2</sup> =17%	2.494 (1.196, 5.202)	2.050 (1.123, 3.745) 0.019	0.146 (0.041 - 0.251)	P=0.625, I <sup>2</sup> =0%	P=0.555, I <sup>2</sup> =0%	P=0.905, I <sup>2</sup> =0%	P=0.080

Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL												
Respiratory, thoracic and mediastinal disorders	Cough	20.8% (14.7, 28.6)	4.1% (1.3, 11.9)	P=0.008, I <sup>2</sup> =85.6%	P=0.522, I <sup>2</sup> =0%	6.157 (1.797, 21.099)	5.007 (1.580, 15.867) 0.006	0.152 (0.077 - 0.228)	P=0.760, I <sup>2</sup> =0%	P=0.865, I <sup>2</sup> =0%	P=0.040, I <sup>2</sup> =7629%	P=0.002
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.979
Investigations		44.5% (33.7, 56.0)	52.0% (36.6, 67.0)	P=0.001, I <sup>2</sup> =91.5%	P=0.001, I <sup>2</sup> =90%	0.668 (0.302, 1.479)	0.827 (0.575, 1.190) 0.307	-0.048 (-0.144 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.356
Investigations	Blood glucose increased	13.4% (7.6, 22.5)	29.7% (18.1, 44.8)	P=0.022, I <sup>2</sup> =80.9%	P=0.010, I <sup>2</sup> =85%	0.353 (0.139, 0.892)	0.453 (0.225, 0.912) 0.026	-0.090 (-0.177 - -0.004)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.623

Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE ≥ 10% in any treatment group

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL												
Investigations	Insulin-like growth factor increased	26.8% (18.2, 37.7)	6.0% (2.1, 15.9)	P=0.004, I <sup>2</sup> =88%	P=0.204, I <sup>2</sup> =38%	4.900 (1.356, 17.703)	3.746 (1.194, 11.759) 0.024	0.104 (0.037 - 0.172)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.957
Investigations	Low density lipoprotein increased	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.979
Gastrointestinal disorders		21.1% (15.3, 28.5)	18.5% (11.2, 28.9)	P=0.694, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =42%	1.239 (0.616, 2.492)	1.190 (0.673, 2.103) 0.55	0.034 (-0.074 - 0.141)	P=0.188, I <sup>2</sup> =4226%	P=0.187, I <sup>2</sup> =4264%	P=0.190, I <sup>2</sup> =4173%	P=0.622
Gastrointestinal disorders	Vomiting	8.9% (4.6, 16.6)	3.7% (1.1, 12.1)	P=0.054, I <sup>2</sup> =73%	P=0.390, I <sup>2</sup> =0%	2.294 (0.464, 11.348)	2.158 (0.480, 9.693) 0.316	0.029 (-0.020 - 0.079)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.437

Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL												
Gastrointestinal disorders	Diarrhoea	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.750
General disorders and administration site conditions		20.4% (14.7, 27.7)	20.9% (13.2, 31.5)	P=0.841, I <sup>2</sup> =0%	P=0.202, I <sup>2</sup> =39%	1.009 (0.512, 1.990)	1.007 (0.586, 1.732) 0.979	0.001 (-0.109 - 0.112)	P=0.248, I <sup>2</sup> =2520%	P=0.249, I <sup>2</sup> =2487%	P=0.242, I <sup>2</sup> =2710%	P=0.569
General disorders and administration site conditions	Pyrexia	17.1% (11.8, 24.0)	12.1% (6.4, 21.7)	P=0.637, I <sup>2</sup> =0%	P=0.247, I <sup>2</sup> =25%	1.589 (0.704, 3.590)	1.492 (0.732, 3.043) 0.271	0.056 (-0.037 - 0.149)	P=0.214, I <sup>2</sup> =3526%	P=0.213, I <sup>2</sup> =3566%	P=0.223, I <sup>2</sup> =3261%	P=0.532

Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE ≥ 10% in any treatment group

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL												
Nervous system disorders		8.4% (4.4, 15.3)	15.3% (8.9, 25.0)	P=0.050, I <sup>2</sup> =74%	P=0.629, I <sup>2</sup> =0%	0.361 (0.143, 0.908)	0.404 (0.179, 0.912) 0.029	-0.091 (-0.178 - -0.003)	P=0.145, I <sup>2</sup> =5293%	P=0.130, I <sup>2</sup> =5647%	P=0.548, I <sup>2</sup> =0%	P=0.193
Nervous system disorders	Headache	8.9% (4.6, 16.6)	12.8% (7.0, 22.2)	P=0.054, I <sup>2</sup> =73%	P=0.585, I <sup>2</sup> =0%	0.393 (0.146, 1.056)	0.431 (0.179, 1.041) 0.061	-0.072 (-0.153 - -0.010)	P=0.102, I <sup>2</sup> =6269%	P=0.094, I <sup>2</sup> =6438%	P=0.399, I <sup>2</sup> =0%	P=0.253
Injury, poisoning and procedural complications		8.9% (4.6, 16.6)	9.9% (4.3, 21.0)	P=0.054, I <sup>2</sup> =73%	P=0.114, I <sup>2</sup> =60%	0.847 (0.258, 2.779)	0.863 (0.302, 2.469) 0.784	-0.009 (-0.072 - -0.054)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.374



Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL												
Metabolism and nutrition disorders		6.9% (3.2, 14.2)	12.8% (6.0, 25.2)	P=0.074, I <sup>2</sup> =68.7%	P=0.066, I <sup>2</sup> =71%	0.492 (0.147, 1.648)	0.535 (0.185, 1.546) 0.248	-0.035 (-0.100 - 0.029)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.289
Metabolism and nutrition disorders	Hypercholesterolaemia	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.979
Metabolism and nutrition disorders	Hypertriglyceridaemia	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.505
Musculoskeletal and connective tissue disorders		8.9% (4.6, 16.6)	7.7% (3.1, 18.1)	P=0.054, I <sup>2</sup> =73%	P=0.163, I <sup>2</sup> =49%	1.088 (0.307, 3.857)	1.079 (0.346, 3.369) 0.896	0.004 (-0.055 - 0.063)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.508

Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL												
Musculoskeletal and connective tissue disorders	Pain in extremity	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.578
Eye disorders		10.8% (5.8, 19.2)	6.0% (2.1, 15.9)	P=0.034, I <sup>2</sup> =77.7%	P=0.204, I <sup>2</sup> =38%	1.694 (0.430, 6.670)	1.606 (0.462, 5.581) 0.456	0.023 (-0.033 - 0.079)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.510
Skin and subcutaneous tissue disorders		10.8% (5.8, 19.2)	3.9% (1.1, 12.6)	P=0.034, I <sup>2</sup> =77.7%	P=0.339, I <sup>2</sup> =0%	2.613 (0.535, 12.765)	2.408 (0.548, 10.587) 0.245	0.036 (-0.015 - 0.086)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.399

Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL												
Endocrine disorders		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.854
Blood and lymphatic system disorders		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.750

Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL												
Any adverse event		77.0% (60.5, 88.0)	70.4% (48.6, 85.6)	P=0.036, I <sup>2</sup> =77.2%	P=0.054, I <sup>2</sup> =73%	2.153 (0.615, 7.531)	1.124 (0.914, 1.383) 0.267	0.095 (-0.067 - 0.258)	P=0.485, I <sup>2</sup> =0%	P=0.605, I <sup>2</sup> =0%	P=0.760, I <sup>2</sup> =0%	
Infections and infestations		51.7% (39.0, 64.2)	69.0% (49.9, 83.2)	P=1.000, I <sup>2</sup> =0%	P=0.239, I <sup>2</sup> =28%	0.459 (0.180, 1.171)	0.739 (0.525, 1.040) 0.083	-0.183 (-0.391 - 0.026)	P=0.319, I <sup>2</sup> =0%	P=0.411, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	
Infections and infestations	Upper respiratory tract infection	30.2% (19.1, 44.2)	49.1% (27.2, 71.4)	P=0.024, I <sup>2</sup> =80.4%	P=0.004, I <sup>2</sup> =88%	0.595 (0.209, 1.697)	0.752 (0.429, 1.319) 0.321	-0.091 (-0.278 - 0.096)	P=0.167, I <sup>2</sup> =4758%	P=0.247, I <sup>2</sup> =2543%	P=0.038, I <sup>2</sup> =7684%	

Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL												
Infections and infestations	Nasopharyngitis	5.5% (1.8, 15.6)	16.9% (7.2, 34.8)	P=0.561, I <sup>2</sup> =0%	P=0.626, I <sup>2</sup> =0%	0.270 (0.059, 1.228)	0.310 (0.080, 1.206) 0.091	-0.115 (-0.260 - 0.030)	P=0.879, I <sup>2</sup> =0%	P=0.844, I <sup>2</sup> =0%	P=0.824, I <sup>2</sup> =0%	
Infections and infestations	Pharyngitis	5.2% (1.5, 16.3)	9.9% (2.8, 29.0)	P=0.358, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	0.481 (0.061, 3.810)	0.517 (0.081, 3.317) 0.487	-0.032 (-0.131 - 0.066)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pharyngitis streptococcal	1.7% (0.2, 10.9)	20.5% (8.2, 42.7)	P=1.000, I <sup>2</sup> =0%	P=0.118, I <sup>2</sup> =59%	NA (NA, NA)	NA (NA, NA) NA	-0.133 (-0.255 - -0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Tonsillitis	5.2% (1.5, 16.3)	9.9% (2.8, 29.0)	P=0.358, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	0.481 (0.061, 3.810)	0.517 (0.081, 3.317) 0.487	-0.032 (-0.131 - 0.066)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL												
Infections and infestations	Respiratory tract infection	2.7% (0.5, 12.3)	9.9% (2.8, 29.0)	P=0.671, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	0.232 (0.019, 2.797)	0.259 (0.025, 2.627) 0.253	-0.049 (-0.144 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Gastroenteritis	1.7% (0.2, 10.9)	9.9% (2.8, 29.0)	P=1.000, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.067 (-0.156 - 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders		31.1% (20.6, 44.1)	33.7% (19.1, 52.2)	P=0.571, I <sup>2</sup> =0%	P=0.441, I <sup>2</sup> =0%	0.899 (0.349, 2.315)	0.931 (0.495, 1.751) 0.825	-0.023 (-0.228 - 0.182)	P=0.771, I <sup>2</sup> =0%	P=0.782, I <sup>2</sup> =0%	P=0.757, I <sup>2</sup> =0%	

Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL												
Respiratory, thoracic and mediastinal disorders	Cough	17.9% (9.5, 31.2)	31.0% (16.8, 50.1)	P=0.087, I <sup>2</sup> =65.9%	P=0.239, I <sup>2</sup> =28%	0.408 (0.137, 1.218)	0.517 (0.235, 1.139) 0.102	-0.145 (-0.329 - 0.039)	P=0.689, I <sup>2</sup> =0%	P=0.561, I <sup>2</sup> =0%	P=0.879, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	5.2% (1.5, 16.3)	9.9% (2.8, 29.0)	P=0.358, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	0.481 (0.061, 3.810)	0.517 (0.081, 3.317) 0.487	-0.032 (-0.131 - 0.066)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations		48.3% (31.5, 65.5)	37.5% (18.7, 60.9)	P=0.004, I <sup>2</sup> =88.2%	P=0.031, I <sup>2</sup> =79%	1.407 (0.403, 4.914)	1.182 (0.628, 2.226) 0.604	0.043 (-0.111 - 0.196)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood glucose increased	16.8% (7.9, 32.2)	26.1% (11.5, 49.1)	P=0.068, I <sup>2</sup> =70%	P=0.075, I <sup>2</sup> =69%	0.522 (0.129, 2.116)	0.621 (0.226, 1.704) 0.355	-0.063 (-0.207 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL												
Investigations	Insulin-like growth factor increased	23.0% (12.0, 39.5)	3.1% (0.4, 19.1)	P=0.036, I <sup>2</sup> =77.2%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.138 (0.049 - 0.227)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Low density lipoprotein increased	5.2% (1.5, 16.3)	9.9% (2.8, 29.0)	P=0.358, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	0.481 (0.061, 3.810)	0.517 (0.081, 3.317) 0.487	-0.032 (-0.131 - 0.066)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders		18.4% (10.2, 31.1)	20.0% (9.3, 37.9)	P=0.175, I <sup>2</sup> =45.6%	P=1.000, I <sup>2</sup> =0%	0.833 (0.270, 2.567)	0.862 (0.347, 2.144) 0.75	-0.028 (-0.201 - 0.145)	P=0.390, I <sup>2</sup> =0%	P=0.382, I <sup>2</sup> =0%	P=0.430, I <sup>2</sup> =0%	
Gastrointestinal disorders	Vomiting	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL												
Gastrointestinal disorders	Diarrhoea	2.7% (0.5, 12.3)	9.9% (2.8, 29.0)	P=0.671, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	0.232 (0.019, 2.797)	0.259 (0.025, 2.627) 0.253	-0.049 (-0.144 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions		15.5% (7.9, 28.2)	20.0% (9.3, 37.9)	P=0.145, I <sup>2</sup> =52.9%	P=1.000, I <sup>2</sup> =0%	0.640 (0.199, 2.057)	0.690 (0.263, 1.805) 0.449	-0.062 (-0.230 - 0.106)	P=0.317, I <sup>2</sup> =31%	P=0.301, I <sup>2</sup> =640%	P=0.416, I <sup>2</sup> =0%	
General disorders and administration site conditions	Pyrexia	13.1% (6.4, 25.2)	13.3% (5.1, 30.6)	P=0.241, I <sup>2</sup> =27.2%	P=1.000, I <sup>2</sup> =0%	0.892 (0.239, 3.328)	0.905 (0.288, 2.849) 0.865	-0.013 (-0.160 - 0.135)	P=0.457, I <sup>2</sup> =0%	P=0.454, I <sup>2</sup> =0%	P=0.488, I <sup>2</sup> =0%	

Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL												
Nervous system disorders		16.8% (7.9, 32.2)	9.9% (2.8, 29.0)	P=0.068, I <sup>2</sup> =70%	P=0.336, I <sup>2</sup> =0%	1.696 (0.298, 9.649)	1.552 (0.355, 6.775) 0.559	0.037 (-0.076 - 0.150)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Nervous system disorders	Headache	13.8% (6.0, 28.4)	5.2% (1.0, 22.0)	P=0.096, I <sup>2</sup> =63.8%	P=0.654, I <sup>2</sup> =0%	2.917 (0.309, 27.560)	2.586 (0.331, 20.181) 0.365	0.053 (-0.041 - 0.147)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications		16.8% (7.9, 32.2)	5.2% (1.0, 22.0)	P=0.068, I <sup>2</sup> =70%	P=0.654, I <sup>2</sup> =0%	3.652 (0.397, 33.587)	3.103 (0.410, 23.469) 0.273	0.070 (-0.028 - 0.168)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatropin in Mean (95%CI)	Daily somatropin in Mean (95%CI)	Lonapeg somatropin in	Daily somatropin in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL												
Metabolism and nutrition disorders		16.8% (7.9, 32.2)	9.9% (2.8, 29.0)	P=0.068, I <sup>2</sup> =70%	P=0.336, I <sup>2</sup> =0%	1.696 (0.298, 9.649)	1.552 (0.355, 6.775) 0.559	0.037 (-0.076 - 0.150)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Hypercholesterolaemia	5.2% (1.5, 16.3)	9.9% (2.8, 29.0)	P=0.358, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	0.481 (0.061, 3.810)	0.517 (0.081, 3.317) 0.487	-0.032 (-0.131 - 0.066)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Hypertriglyceridaemia	7.9% (2.8, 20.5)	3.1% (0.4, 19.1)	P=0.216, I <sup>2</sup> =34.6%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.052 (-0.005 - 0.109)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders		5.2% (1.5, 16.3)	9.9% (2.8, 29.0)	P=0.358, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	0.481 (0.061, 3.810)	0.517 (0.081, 3.317) 0.487	-0.032 (-0.131 - 0.066)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL												
Musculoskeletal and connective tissue disorders	Pain in extremity	1.7% (0.2, 10.9)	9.9% (2.8, 29.0)	P=1.000, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.067 (-0.156 - 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.000 (0.000 - 0.000)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.28.m Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration, AE ≥ 10% in any treatment group

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Lonapeg somatrop in Mean (95%CI)	Daily somatrop in Mean (95%CI)	Lonapeg somatrop in	Daily somatrop in	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL												
Endocrine disorders		7.9% (2.8, 20.5)	9.9% (2.8, 29.0)	P=0.216, I <sup>2</sup> =34.6%	P=0.336, I <sup>2</sup> =0%	0.750 (0.111, 5.060)	0.776 (0.145, 4.151) 0.767	-0.015 (-0.118 - 0.088)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders		2.7% (0.5, 12.3)	9.9% (2.8, 29.0)	P=0.671, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	0.232 (0.019, 2.797)	0.259 (0.025, 2.627) 0.253	-0.049 (-0.144 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.												

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Any adverse event			91.0% (81.5, 95.9)	86.1% (70.7, 94.1)	P=0.015 , I <sup>2</sup> =76.5 %	P=0.042 , I <sup>2</sup> =69%							P=0.681
Any adverse event		Mild	73.1% (61.3, 82.4)	66.7% (50.0, 80.0)	P=0.000 , I <sup>2</sup> =91.1 %	P=0.002 , I <sup>2</sup> =88%	1.429 (0.524, 3.901)	1.086 (0.854, 1.382) 0.5	0.058 (-0.107 - 0.223)	P=0.735, I <sup>2</sup> =0%	P=0.422, I <sup>2</sup> =0%	P=0.544, I <sup>2</sup> =0%	P=0.812
Any adverse event		Moderate	16.4% (9.3, 27.3)	19.4% (9.6, 35.5)	P=0.009 , I <sup>2</sup> =83.5 %	P=0.051 , I <sup>2</sup> =71%	0.819 (0.270, 2.486)	0.864 (0.385, 1.939) 0.723	-0.026 (-0.175 - 0.122)	P=0.935, I <sup>2</sup> =0%	P=0.893, I <sup>2</sup> =0%	P=0.908, I <sup>2</sup> =0%	P=0.754

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Any adverse event		Severe	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.808
Infections and infestations			70.1% (58.2, 79.9)	77.8% (61.5, 88.5)	P=0.165, I <sup>2</sup> =48.1%	P=0.124, I <sup>2</sup> =56%							P=0.783
Infections and infestations		Mild	61.2% (49.1, 72.0)	58.3% (41.9, 73.1)	P=0.026, I <sup>2</sup> =79.2%	P=0.003, I <sup>2</sup> =87%	1.117 (0.461, 2.707)	1.039 (0.761, 1.420) 0.808	0.023 (-0.162 - 0.209)	P=0.297, I <sup>2</sup> =805%	P=0.259, I <sup>2</sup> =2154%	P=0.269, I <sup>2</sup> =1818%	P=0.935
Infections and infestations		Moderate	7.5% (3.1, 16.7)	19.4% (9.6, 35.5)	P=0.042, I <sup>2</sup> =68.7%	P=0.051, I <sup>2</sup> =71%	0.311 (0.085, 1.136)	0.394 (0.141, 1.099) 0.075	-0.117 (-0.256 - 0.022)	P=0.818, I <sup>2</sup> =0%	P=0.684, I <sup>2</sup> =0%	P=0.350, I <sup>2</sup> =0%	P=0.334

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations		Severe	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.808
Infections and infestations	Upper respiratory tract infection		37.3% (26.6, 49.4)	52.8% (36.7, 68.3)	P=0.000, I <sup>2</sup> =90.8%	P=0.000, I <sup>2</sup> =0%							P=0.341
Infections and infestations	Upper respiratory tract infection	Mild	37.3% (26.6, 49.4)	47.2% (31.7, 63.3)	P=0.000, I <sup>2</sup> =90.8%	P=0.000, I <sup>2</sup> =0%	0.498 (0.175, 1.418)	0.773 (0.536, 1.116) 0.169	-0.108 (-0.269 - 0.053)	P=0.200, I <sup>2</sup> =390%	P=0.321, I <sup>2</sup> =0%	P=0.012, I <sup>2</sup> =8415%	P=0.279



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Upper respiratory tract infection	Moderate	0%	5.6% (1.4, 19.7)	P=1.000, I <sup>2</sup> =0%	P=0.153, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.056 (-0.131 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.814
Infections and infestations	Upper respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Nasopharyngitis		7.5% (3.1, 16.7)	11.1% (4.2, 26.1)	P=0.042, I <sup>2</sup> =68.7%	P=0.633, I <sup>2</sup> =0%							P=0.838
Infections and infestations	Nasopharyngitis	Mild	7.5% (3.1, 16.7)	5.6% (1.4, 19.7)	P=0.042, I <sup>2</sup> =68.7%	P=0.743, I <sup>2</sup> =0%	1.409 (0.258, 7.686)	1.372 (0.285, 6.601) 0.693	0.021 (-0.077 - 0.118)	P=0.394, I <sup>2</sup> =0%	P=0.406, I <sup>2</sup> =0%	P=0.281, I <sup>2</sup> =1405%	P=0.361

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Nasopharyngitis	Moderate	0%	5.6% (1.4, 19.7)	P=1.000, I <sup>2</sup> =0%	P=0.743, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.055 (-0.130 - 0.019)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.756, I <sup>2</sup> =0%	P=0.310
Infections and infestations	Nasopharyngitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Pharyngitis		7.5% (3.1, 16.7)	11.1% (4.2, 26.1)	P=0.042, I <sup>2</sup> =68.7%	P=0.119, I <sup>2</sup> =52%							P=0.509
Infections and infestations	Pharyngitis	Mild	6.0% (2.3, 14.9)	11.1% (4.2, 26.1)	P=0.113, I <sup>2</sup> =52.6%	P=0.119, I <sup>2</sup> =52%	0.503 (0.113, 2.236)	0.551 (0.152, 1.999) 0.365	-0.049 (-0.164 - 0.065)	P=0.989, I <sup>2</sup> =0%	P=0.966, I <sup>2</sup> =0%	P=0.512, I <sup>2</sup> =0%	P=0.725

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Pharyngitis	Moderate	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706
Infections and infestations	Pharyngitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Respiratory tract infection		7.5% (3.1, 16.7)	5.6% (1.4, 19.7)	P=0.042, I <sup>2</sup> =68.7%	P=0.743, I <sup>2</sup> =0%							P=0.742
Infections and infestations	Respiratory tract infection	Mild	7.5% (3.1, 16.7)	2.8% (0.4, 17.3)	P=0.042, I <sup>2</sup> =68.7%	P=0.317, I <sup>2</sup> =0%	2.754 (0.330, 22.974)	2.712 (0.328, 22.411) 0.355	0.048 (-0.037 - 0.133)	P=0.201, I <sup>2</sup> =3875%	P=0.206, I <sup>2</sup> =3748%	P=0.082, I <sup>2</sup> =6689%	P=0.493

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Respiratory tract infection	Moderate	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.081 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.350
Infections and infestations	Respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Bronchitis		14.9% (8.2, 25.6)	11.1% (4.2, 26.1)	P=0.202, I <sup>2</sup> =29.6%	P=0.633, I <sup>2</sup> =0%							P=0.746
Infections and infestations	Bronchitis	Mild	11.9% (6.1, 22.1)	5.6% (1.4, 19.7)	P=0.096, I <sup>2</sup> =50.7%	P=0.153, I <sup>2</sup> =0%	2.328 (0.454, 11.939)	2.107 (0.484, 9.163) 0.32	0.062 (-0.044 - 0.168)	P=0.809, I <sup>2</sup> =0%	P=0.825, I <sup>2</sup> =0%	P=0.548, I <sup>2</sup> =0%	P=0.695

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Bronchitis	Moderate	1.5% (0.2, 9.8)	5.6% (1.4, 19.7)	P=0.158, I <sup>2</sup> =0%	P=0.046, I <sup>2</sup> =0%	0.250 (0.021, 3.041)	0.280 (0.028, 2.820) 0.28	-0.039 (-0.118 - 0.039)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.752
Infections and infestations	Bronchitis	Severe	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715
Infections and infestations	Tonsillitis		6.0% (2.3, 14.9)	8.3% (2.7, 22.9)	P=0.589, I <sup>2</sup> =0%	P=0.835, I <sup>2</sup> =0%							P=0.964
Infections and infestations	Tonsillitis	Mild	6.0% (2.3, 14.9)	5.6% (1.4, 19.7)	P=0.589, I <sup>2</sup> =0%	P=0.153, I <sup>2</sup> =0%	1.064 (0.184, 6.158)	1.059 (0.207, 5.414) 0.945	0.003 (-0.090 - 0.097)	P=0.647, I <sup>2</sup> =0%	P=0.646, I <sup>2</sup> =0%	P=0.653, I <sup>2</sup> =0%	P=0.837

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Tonsillitis	Moderate	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.081 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.740
Infections and infestations	Tonsillitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Rhinitis		1.5% (0.2, 9.8)	5.6% (1.4, 19.7)	P=0.158, I <sup>2</sup> =0%	P=0.046, I <sup>2</sup> =0%							P=0.230
Infections and infestations	Rhinitis	Mild	1.5% (0.2, 9.8)	5.6% (1.4, 19.7)	P=0.158, I <sup>2</sup> =0%	P=0.046, I <sup>2</sup> =0%	0.250 (0.021, 3.041)	0.280 (0.028, 2.820) 0.28	-0.039 (-0.118 - 0.039)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.230

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Rhinitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Rhinitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Gastroenteritis		1.5% (0.2, 9.8)	5.6% (1.4, 19.7)	P=0.331, I <sup>2</sup> =0%	P=0.743, I <sup>2</sup> =0%							P=0.705
Infections and infestations	Gastroenteritis	Mild	1.5% (0.2, 9.8)	5.6% (1.4, 19.7)	P=0.331, I <sup>2</sup> =0%	P=0.743, I <sup>2</sup> =0%	0.256 (0.022, 2.946)	0.265 (0.024, 2.905) 0.277	-0.041 (-0.121 - 0.040)	P=0.595, I <sup>2</sup> =0%	P=0.596, I <sup>2</sup> =0%	P=0.536, I <sup>2</sup> =0%	P=0.562

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Gastroenteritis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Infections and infestations	Gastroenteritis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Sinusitis		4.5% (1.5, 13.0)	0%	P=0.292, I <sup>2</sup> =3%	P=1.000, I <sup>2</sup> =0%							P=0.125
Infections and infestations	Sinusitis	Mild	3.0% (0.7, 11.2)	0%	P=0.711, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.011 - 0.071)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.676, I <sup>2</sup> =0%	P=0.198



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Sinusitis	Moderate	1.5% (0.2, 9.8)	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.675
Infections and infestations	Sinusitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Pneumonia		4.5% (1.5, 13.0)	2.8% (0.4, 17.3)	P=0.883, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.132
Infections and infestations	Pneumonia	Mild	3.0% (0.7, 11.2)	2.8% (0.4, 17.3)	P=0.168, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	1.050 (0.090, 12.264)	1.048 (0.100, 10.923) 0.969	0.001 (-0.065 - 0.068)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.471

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Pneumonia	Moderate	1.5% (0.2, 9.8)	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.324
Infections and infestations	Pneumonia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Pharyngitis streptococcal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.845
Infections and infestations	Pharyngitis streptococcal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.976
Infections and infestations	Pharyngitis streptococcal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.750

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Pharyngitis streptococcal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Viral infection		3.0% (0.7, 11.2)	0%	P=0.044, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.836
Infections and infestations	Viral infection	Mild	3.0% (0.7, 11.2)	0%	P=0.044, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.031 (-0.011 - 0.072)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.917
Infections and infestations	Viral infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Viral infection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Infections and infestations	Ear infection		1.5% (0.2, 9.8)	0%	P=0.158 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.830
Infections and infestations	Ear infection	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Infections and infestations	Ear infection	Moderate	1.5% (0.2, 9.8)	0%	P=0.158 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.759

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Ear infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Respiratory tract infection viral		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%							P=0.366
Infections and infestations	Respiratory tract infection viral	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.081 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.491
Infections and infestations	Respiratory tract infection viral	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Respiratory tract infection viral	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Conjunctivitis		3.0% (0.7, 11.2)	2.8% (0.4, 17.3)	P=0.711, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.918
Infections and infestations	Conjunctivitis	Mild	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	0.512 (0.030, 8.604)	0.524 (0.034, 7.979) 0.642	-0.013 (-0.074, 0.047)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.701
Infections and infestations	Conjunctivitis	Moderate	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014, 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Conjunctivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Gastroenteritis viral		1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.158, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.564
Infections and infestations	Gastroenteritis viral	Mild	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.158, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	0.547 (0.035, 8.586)	0.547 (0.036, 8.353) 0.664	-0.013 (-0.075, 0.049)	P=0.316, I <sup>2</sup> =53%	P=0.317, I <sup>2</sup> =13%	P=0.344, I <sup>2</sup> =0%	P=0.564
Infections and infestations	Gastroenteritis viral	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Gastroenteritis viral	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Otitis media acute		1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.991
Infections and infestations	Otitis media acute	Mild	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	0.512 (0.030, 8.604)	0.524 (0.034, 7.979) 0.642	-0.013 (-0.074, 0.047)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.701
Infections and infestations	Otitis media acute	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Otitis media acute	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Varicella		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.233
Infections and infestations	Varicella	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.307
Infections and infestations	Varicella	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Infections and infestations	Varicella	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Enteritis infectious		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%							P=0.718
Infections and infestations	Enteritis infectious	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Infections and infestations	Enteritis infectious	Moderate	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.081 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.982
Infections and infestations	Enteritis infectious	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Enterobiasis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.792
Infections and infestations	Enterobiasis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.792
Infections and infestations	Enterobiasis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Infections and infestations	Enterobiasis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Infections and infestations	Influenza		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.807

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Influenza	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Infections and infestations	Influenza	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.556
Infections and infestations	Influenza	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Herpangina		4.5% (1.5, 13.0)	0%	P=0.089, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.493

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Herpangina	Mild	4.5% (1.5, 13.0)	0%	P=0.089, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.044 (-0.005 - 0.093)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.493
Infections and infestations	Herpangina	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Herpangina	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Otitis media		3.0% (0.7, 11.2)	0%	P=0.168, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.332

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Otitis media	Mild	3.0% (0.7, 11.2)	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.029 (-0.011 - 0.070)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.332
Infections and infestations	Otitis media	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Otitis media	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Periodontitis		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.851
Infections and infestations	Periodontitis	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.851

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Periodontitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Periodontitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Urinary tract infection		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%							P=0.983
Infections and infestations	Urinary tract infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Urinary tract infection	Moderate	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.081 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.740
Infections and infestations	Urinary tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Helminthic infection		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Helminthic infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Helminthic infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Helminthic infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Hordeolum		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Hordeolum	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Hordeolum	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Hordeolum	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Pharyngotonsillitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Pharyngotonsillitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Infections and infestations	Pharyngotonsillitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Infections and infestations	Pharyngotonsillitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Pulpitis dental		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.987
Infections and infestations	Pulpitis dental	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.987
Infections and infestations	Pulpitis dental	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Pulpitis dental	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Viral upper respiratory tract infection		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Viral upper respiratory tract infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Viral upper respiratory tract infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Viral upper respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Hand-foot-and-mouth disease		3.0% (0.7, 11.2)	0%	P=0.168, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.578
Infections and infestations	Hand-foot-and-mouth disease	Mild	3.0% (0.7, 11.2)	0%	P=0.168, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.029 (-0.011 - 0.070)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.578
Infections and infestations	Hand-foot-and-mouth disease	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Hand-foot-and-mouth disease	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Laryngitis		1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.997
Infections and infestations	Laryngitis	Mild	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	0.512 (0.030, 8.604)	0.524 (0.034, 7.979) 0.642	-0.013 (-0.074, 0.047)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.997
Infections and infestations	Laryngitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Laryngitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Oral herpes		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.447
Infections and infestations	Oral herpes	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.447
Infections and infestations	Oral herpes	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Oral herpes	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Eczema infected		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.706

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Eczema infected	Mild	1.5% (0.2, 9.8)	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706
Infections and infestations	Eczema infected	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Eczema infected	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Laryngitis viral		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%							P=0.740



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Laryngitis viral	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.081 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.740
Infections and infestations	Laryngitis viral	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Laryngitis viral	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Rotavirus infection		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.706

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Rotavirus infection	Mild	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706
Infections and infestations	Rotavirus infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Rotavirus infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Vulvitis		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.706

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Vulvitis	Mild	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706
Infections and infestations	Vulvitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Vulvitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Appendicitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Infections and infestations	Appendicitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Appendicitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Infections and infestations	Appendicitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741
Infections and infestations	Atypical pneumonia		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741
Infections and infestations	Atypical pneumonia	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Infections and infestations	Atypical pneumonia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Atypical pneumonia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Conjunctivitis bacterial		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Infections and infestations	Conjunctivitis bacterial	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Infections and infestations	Conjunctivitis bacterial	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Conjunctivitis bacterial	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Croup infectious		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.614
Infections and infestations	Croup infectious	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Croup infectious	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Croup infectious	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Cystitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741
Infections and infestations	Cystitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741
Infections and infestations	Cystitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Infections and infestations	Cystitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Infections and infestations	Infected bite		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Infected bite	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741
Infections and infestations	Infected bite	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Infections and infestations	Infected bite	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Infections and infestations	Molluscum contagiosum		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Molluscum contagiosum	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741
Infections and infestations	Molluscum contagiosum	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Infections and infestations	Molluscum contagiosum	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Infections and infestations	Otitis externa		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741
Infections and infestations	Otitis externa	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Otitis externa	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741
Infections and infestations	Otitis externa	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Infections and infestations	Tinea pedis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741
Infections and infestations	Tinea pedis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741
Infections and infestations	Tinea pedis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Tinea pedis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Infections and infestations	Tooth abscess		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741
Infections and infestations	Tooth abscess	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741
Infections and infestations	Tooth abscess	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Tooth abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Bacterial infection		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.737
Infections and infestations	Bacterial infection	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.737
Infections and infestations	Bacterial infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Bacterial infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Folliculitis		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.715
Infections and infestations	Folliculitis	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715
Infections and infestations	Folliculitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Folliculitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Gastrointestinal bacterial infection		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.715
Infections and infestations	Gastrointestinal bacterial infection	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715
Infections and infestations	Gastrointestinal bacterial infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Gastrointestinal bacterial infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Herpes virus infection		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.737
Infections and infestations	Herpes virus infection	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.737
Infections and infestations	Herpes virus infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Herpes virus infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Infectious mononucleosis		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.737

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Infectious mononucleosis	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.737
Infections and infestations	Infectious mononucleosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Infectious mononucleosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Mumps		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.715



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Mumps	Mild	1.5% (0.2, 9.8)	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715
Infections and infestations	Mumps	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Mumps	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Peritonsillar abscess		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.737

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Peritonsillar abscess	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Peritonsillar abscess	Moderate	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.737
Infections and infestations	Peritonsillar abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Sinobronchitis		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.737

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Sinobronchitis	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.737
Infections and infestations	Sinobronchitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Sinobronchitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Subcutaneous abscess		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.715
Infections and infestations	Subcutaneous abscess	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Subcutaneous abscess	Moderate	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715
Infections and infestations	Subcutaneous abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Abscess limb		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Infections and infestations	Abscess limb	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Abscess limb	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Infections and infestations	Abscess limb	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Infections and infestations	Chronic sinusitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.738
Infections and infestations	Chronic sinusitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.738
Infections and infestations	Chronic sinusitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Chronic sinusitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Infections and infestations	Chronic tonsillitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.738
Infections and infestations	Chronic tonsillitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.738
Infections and infestations	Chronic tonsillitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Infections and infestations	Chronic tonsillitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Myringitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Infections and infestations	Myringitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Infections and infestations	Myringitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Myringitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Infections and infestations	Tonsillitis bacterial		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.738
Infections and infestations	Tonsillitis bacterial	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Infections and infestations	Tonsillitis bacterial	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Infections and infestations	Tonsillitis bacterial	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.738
Infections and infestations	Tracheitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.738



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Infections and infestations	Tracheitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Infections and infestations	Tracheitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Infections and infestations	Tracheitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations			38.8% (28.0, 50.9)	25.0% (13.6, 41.5)	P=0.000, I <sup>2</sup> =91.4%	P=0.001, I <sup>2</sup> =0%							P=0.043

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations		Mild	38.8% (28.0, 50.9)	25.0% (13.6, 41.5)	P=0.000, I <sup>2</sup> =91.4%	P=0.001, I <sup>2</sup> =0%	2.210 (0.794, 6.145)	1.518 (0.856, 2.693) 0.153	0.131 (-0.030, 0.292)	P=0.740, I <sup>2</sup> =0%	P=0.608, I <sup>2</sup> =0%	P=0.343, I <sup>2</sup> =0%	P=0.043
Investigations		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood glucose increased		6.0% (2.3, 14.9)	11.1% (4.2, 26.1)	P=0.049, I <sup>2</sup> =0%	P=0.039, I <sup>2</sup> =0%							P=0.929
Investigations	Blood glucose increased	Mild	6.0% (2.3, 14.9)	11.1% (4.2, 26.1)	P=0.049, I <sup>2</sup> =0%	P=0.039, I <sup>2</sup> =0%	0.474 (0.106, 2.112)	0.524 (0.145, 1.896) 0.324	-0.053 (-0.168, 0.061)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.929

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Blood glucose increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood glucose increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Insulin-like growth factor increased		26.9% (17.6, 38.7)	2.8% (0.4, 17.3)	P=0.000, I <sup>2</sup> =85.4%	P=0.317, I <sup>2</sup> =0%							P=0.526
Investigations	Insulin-like growth factor increased	Mild	26.9% (17.6, 38.7)	2.8% (0.4, 17.3)	P=0.000, I <sup>2</sup> =85.4%	P=0.317, I <sup>2</sup> =0%	15.199 (1.849, 124.928)	9.452 (1.346, 66.366) 0.024	0.237 (0.121 - 0.353)	P=0.197, I <sup>2</sup> =3990%	P=0.288, I <sup>2</sup> =1140%	P=0.000, I <sup>2</sup> =9206%	P=0.526

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Insulin-like growth factor increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Insulin-like growth factor increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Low density lipoprotein increased		4.5% (1.5, 13.0)	2.8% (0.4, 17.3)	P=0.089, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.230

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Low density lipoprotein increased	Mild	4.5% (1.5, 13.0)	2.8% (0.4, 17.3)	P=0.089, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	1.615 (0.158, 16.512)	1.571 (0.173, 14.233) 0.688	0.016 (-0.056 - 0.088)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.230
Investigations	Low density lipoprotein increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Low density lipoprotein increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood alkaline phosphatase increased		3.0% (0.7, 11.2)	8.3% (2.7, 22.9)	P=0.168, I <sup>2</sup> =0%	P=0.077, I <sup>2</sup> =0%							P=0.807

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Blood alkaline phosphatase increased	Mild	3.0% (0.7, 11.2)	8.3% (2.7, 22.9)	P=0.168, I <sup>2</sup> =0%	P=0.077, I <sup>2</sup> =0%	0.317 (0.049, 2.056)	0.349 (0.063, 1.937) 0.229	-0.055 (-0.153, 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.807
Investigations	Blood alkaline phosphatase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood alkaline phosphatase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Eosinophil count increased		4.5% (1.5, 13.0)	0%	P=0.883, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.540
Investigations	Eosinophil count increased	Mild	4.5% (1.5, 13.0)	0%	P=0.883, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.045 (-0.005 - 0.094)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.720, I <sup>2</sup> =0%	P=0.540
Investigations	Eosinophil count increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Eosinophil count increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Alanine aminotransferase increased		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.478

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Alanine aminotransferase increased	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.478
Investigations	Alanine aminotransferase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Alanine aminotransferase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood iron increased		1.5% (0.2, 9.8)	5.6% (1.4, 19.7)	P=0.331, I <sup>2</sup> =0%	P=0.153, I <sup>2</sup> =0%							P=0.741



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Blood iron increased	Mild	1.5% (0.2, 9.8)	5.6% (1.4, 19.7)	P=0.331, I <sup>2</sup> =0%	P=0.153, I <sup>2</sup> =0%	0.244 (0.021, 2.853)	0.262 (0.025, 2.731) 0.263	-0.041 (-0.121, 0.039)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.741
Investigations	Blood iron increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood iron increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood phosphorus increased		1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.453

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Blood phosphorus increased	Mild	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	0.512 (0.030, 8.604)	0.524 (0.034, 7.979) 0.642	-0.013 (-0.074, 0.047)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.453
Investigations	Blood phosphorus increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood phosphorus increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood uric acid increased		1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.747

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Blood uric acid increased	Mild	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	0.512 (0.030, 8.604)	0.524 (0.034, 7.979) 0.642	-0.013 (-0.074 - 0.047)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.747
Investigations	Blood uric acid increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood uric acid increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Cortisol decreased		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.909
Investigations	Cortisol decreased	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.909

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Cortisol decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Cortisol decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Aspartate aminotransferase increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.868
Investigations	Aspartate aminotransferase increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.868

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Aspartate aminotransferase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Aspartate aminotransferase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood triglycerides increased		1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.699
Investigations	Blood triglycerides increased	Mild	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	0.512 (0.030, 8.604)	0.524 (0.034, 7.979) 0.642	-0.013 (-0.074, 0.047)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.699
Investigations	Blood triglycerides increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Blood triglycerides increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood glucose abnormal		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.331
Investigations	Blood glucose abnormal	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.331
Investigations	Blood glucose abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Blood glucose abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood thyroid stimulating hormone increased		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.987
Investigations	Blood thyroid stimulating hormone increased	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.987

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Blood thyroid stimulating hormone increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood thyroid stimulating hormone increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	White blood cell count decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.556



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	White blood cell count decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.556
Investigations	White blood cell count decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	White blood cell count decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Tri-iodothyronine free increased		1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.997

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Tri-iodothyronine free increased	Mild	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	0.512 (0.030, 8.604)	0.524 (0.034, 7.979) 0.642	-0.013 (-0.074, 0.047)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.997
Investigations	Tri-iodothyronine free increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Tri-iodothyronine free increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Electrocardiogram T wave peaked		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.990

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Electrocardiogram T wave peaked	Mild	1.5% (0.2, 9.8)	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.990
Investigations	Electrocardiogram T wave peaked	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Electrocardiogram T wave peaked	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood urea increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.574
Investigations	Blood urea increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.574

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Blood urea increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood urea increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood cortisol decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Investigations	Blood cortisol decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Blood cortisol decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood cortisol decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood iron decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Investigations	Blood iron decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Investigations	Blood iron decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Blood iron decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Cortisol free urine decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Investigations	Cortisol free urine decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Investigations	Cortisol free urine decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Cortisol free urine decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Thyroxine decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Investigations	Thyroxine decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Investigations	Thyroxine decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Thyroxine decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Transaminases increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Investigations	Transaminases increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Investigations	Transaminases increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Transaminases increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Basophil count increased		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.715



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Basophil count increased	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715
Investigations	Basophil count increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Basophil count increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood cholesterol increased		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.715

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Blood cholesterol increased	Mild	1.5% (0.2, 9.8)	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715
Investigations	Blood cholesterol increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood cholesterol increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood lactate dehydrogenase increased		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.737

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Blood lactate dehydrogenase increased	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.737
Investigations	Blood lactate dehydrogenase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood lactate dehydrogenase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood potassium increased		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.737

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Blood potassium increased	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.737
Investigations	Blood potassium increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood potassium increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood pressure increased		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.737

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Blood pressure increased	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.737
Investigations	Blood pressure increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Blood pressure increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Electrocardiogram ST segment abnormal		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.737

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Electrocardiogram ST segment abnormal	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.737
Investigations	Electrocardiogram ST segment abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Electrocardiogram ST segment abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Haemoglobin decreased		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.737
Investigations	Haemoglobin decreased	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.737

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Haemoglobin decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Haemoglobin decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Electrocardiogram high voltage		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Investigations	Electrocardiogram high voltage	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Electrocardiogram high voltage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Electrocardiogram high voltage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Hepatic enzyme abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
Investigations	Hepatic enzyme abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
Investigations	Hepatic enzyme abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Hepatic enzyme abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Hepatic enzyme increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
Investigations	Hepatic enzyme increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
Investigations	Hepatic enzyme increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Hepatic enzyme increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Lipids increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
Investigations	Lipids increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
Investigations	Lipids increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Lipids increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Liver function test abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
Investigations	Liver function test abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
Investigations	Liver function test abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Liver function test abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Thyroid function test abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
Investigations	Thyroid function test abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
Investigations	Thyroid function test abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Investigations	Thyroid function test abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Thyroxine free decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Investigations	Thyroxine free decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Investigations	Thyroxine free decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Investigations	Thyroxine free decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders			38.8% (28.0, 50.9)	16.7% (7.7, 32.5)	P=0.375, I <sup>2</sup> =0%	P=0.199, I <sup>2</sup> =26%							P=0.213
Respiratory, thoracic and mediastinal disorders		Mild	35.8% (25.3, 47.9)	13.9% (5.9, 29.3)	P=0.114, I <sup>2</sup> =57.7%	P=0.331, I <sup>2</sup> =0%	3.554 (1.200, 10.528)	2.554 (1.076, 6.060) 0.033	0.217 (0.058 - 0.376)	P=0.880, I <sup>2</sup> =0%	P=0.754, I <sup>2</sup> =0%	P=0.607, I <sup>2</sup> =0%	P=0.202

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders		Moderate	3.0% (0.7, 11.2)	2.8% (0.4, 17.3)	P=0.044, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	1.094 (0.101, 11.830)	1.094 (0.103, 11.641) 0.941	0.003 (-0.066, 0.072)	P=0.192, I <sup>2</sup> =4137%	P=0.196, I <sup>2</sup> =4032%	P=0.187, I <sup>2</sup> =4263%	P=0.930
Respiratory, thoracic and mediastinal disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Respiratory, thoracic and mediastinal disorders	Cough		28.4% (18.9, 40.2)	8.3% (2.7, 22.9)	P=0.075, I <sup>2</sup> =65%	P=0.077, I <sup>2</sup> =0%							P=0.131

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Cough	Mild	26.9% (17.6, 38.7)	5.6% (1.4, 19.7)	P=0.027 , I <sup>2</sup> =75.5 %	P=0.153 , I <sup>2</sup> =0%	6.832 (1.420, 32.868)	4.749 (1.195, 18.880) 0.027	0.210 (0.083 - 0.337)	P=0.71 1, I <sup>2</sup> =0%	P=0.77 1, I <sup>2</sup> =0%	P=0.14 4, I <sup>2</sup> =530 4%	P=0.164
Respiratory, thoracic and mediastinal disorders	Cough	Moderate	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.158 , I <sup>2</sup> =0%	P=0.317 , I <sup>2</sup> =0%	0.547 (0.035, 8.586)	0.547 (0.036, 8.353) 0.664	-0.013 (-0.075 - 0.049)	P=0.31 6, I <sup>2</sup> =53%	P=0.31 7, I <sup>2</sup> =13%	P=0.34 4, I <sup>2</sup> =0%	P=0.479
Respiratory, thoracic and mediastinal disorders	Cough	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea		4.5% (1.5, 13.0)	2.8% (0.4, 17.3)	P=0.089, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.114
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Mild	4.5% (1.5, 13.0)	2.8% (0.4, 17.3)	P=0.089, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	1.615 (0.158, 16.512)	1.571 (0.173, 14.233) 0.688	0.016 (-0.056, 0.088)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.114
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic		3.0% (0.7, 11.2)	5.6% (1.4, 19.7)	P=0.168 , I <sup>2</sup> =0%	P=0.743 , I <sup>2</sup> =0%							P=0.640
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Mild	3.0% (0.7, 11.2)	5.6% (1.4, 19.7)	P=0.168 , I <sup>2</sup> =0%	P=0.743 , I <sup>2</sup> =0%	0.518 (0.070, 3.858)	0.530 (0.076, 3.695) 0.522	-0.026 (-0.111 - 0.059)	P=0.391, I <sup>2</sup> =0%	P=0.394, I <sup>2</sup> =0%	P=0.401, I <sup>2</sup> =0%	P=0.640

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Asthma		3.0% (0.7, 11.2)	2.8% (0.4, 17.3)	P=0.711, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.986
Respiratory, thoracic and mediastinal disorders	Asthma	Mild	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	0.512 (0.030, 8.604)	0.524 (0.034, 7.979) 0.642	-0.013 (-0.074, 0.047)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.499
Respiratory, thoracic and mediastinal disorders	Asthma	Moderate	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014, 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.439

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Asthma	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Respiratory, thoracic and mediastinal disorders	Respiratory disorder		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Mild	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.671

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Respiratory, thoracic and mediastinal disorders	Epistaxis		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.894

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Epistaxis	Mild	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.671
Respiratory, thoracic and mediastinal disorders	Epistaxis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Respiratory, thoracic and mediastinal disorders	Epistaxis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Nasal congestion		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.997
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.770



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Respiratory, thoracic and mediastinal disorders	Sinus congestion		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.865

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Mild	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.977
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Wheezing		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.792
Respiratory, thoracic and mediastinal disorders	Wheezing	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Respiratory, thoracic and mediastinal disorders	Wheezing	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Wheezing	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Respiratory, thoracic and mediastinal disorders	Allergic cough		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.987
Respiratory, thoracic and mediastinal disorders	Allergic cough	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.987

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Allergic cough	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Respiratory, thoracic and mediastinal disorders	Allergic cough	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.987
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Respiratory, thoracic and mediastinal disorders	Laryngospasm		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.706
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Moderate	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.715

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Nasal obstruction		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.715
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Respiratory, thoracic and mediastinal disorders	Productive cough		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.715
Respiratory, thoracic and mediastinal disorders	Productive cough	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Productive cough	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Respiratory, thoracic and mediastinal disorders	Productive cough	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders			16.4% (9.3, 27.3)	16.7% (7.7, 32.5)	P=0.203, I <sup>2</sup> =38.1%	P=0.010, I <sup>2</sup> =0%							P=0.312
Gastrointestinal disorders		Mild	16.4% (9.3, 27.3)	16.7% (7.7, 32.5)	P=0.203, I <sup>2</sup> =38.1%	P=0.010, I <sup>2</sup> =0%	0.981 (0.341, 2.822)	0.984 (0.390, 2.479) 0.972	-0.003 (-0.158, 0.153)	P=0.034, I <sup>2</sup> =7778%	P=0.040, I <sup>2</sup> =7638%	P=0.008, I <sup>2</sup> =8596%	P=0.238
Gastrointestinal disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.750

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Gastrointestinal disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Diarrhoea		6.0% (2.3, 14.9)	5.6% (1.4, 19.7)	P=0.589, I <sup>2</sup> =0%	P=0.153, I <sup>2</sup> =0%							P=0.752
Gastrointestinal disorders	Diarrhoea	Mild	6.0% (2.3, 14.9)	5.6% (1.4, 19.7)	P=0.589, I <sup>2</sup> =0%	P=0.153, I <sup>2</sup> =0%	1.064 (0.184, 6.158)	1.059 (0.207, 5.414) 0.945	0.003 (-0.090 - 0.097)	P=0.647, I <sup>2</sup> =0%	P=0.646, I <sup>2</sup> =0%	P=0.653, I <sup>2</sup> =0%	P=0.752
Gastrointestinal disorders	Diarrhoea	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Diarrhoea	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Gastrointestinal disorders	Vomiting		3.0% (0.7, 11.2)	0%	P=0.044, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.885
Gastrointestinal disorders	Vomiting	Mild	3.0% (0.7, 11.2)	0%	P=0.044, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.031 (-0.011 - 0.072)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.916
Gastrointestinal disorders	Vomiting	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Gastrointestinal disorders	Vomiting	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Gastrointestinal disorders	Nausea		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.645
Gastrointestinal disorders	Nausea	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.531
Gastrointestinal disorders	Nausea	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Nausea	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Dyspepsia		3.0% (0.7, 11.2)	2.8% (0.4, 17.3)	P=0.044, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.934

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Gastrointestinal disorders	Dyspepsia	Mild	3.0% (0.7, 11.2)	2.8% (0.4, 17.3)	P=0.044, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	1.094 (0.101, 11.830)	1.094 (0.103, 11.641) 0.941	0.003 (-0.066, 0.072)	P=0.192, I <sup>2</sup> =4137%	P=0.196, I <sup>2</sup> =4032%	P=0.187, I <sup>2</sup> =4263%	P=0.934
Gastrointestinal disorders	Dyspepsia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Dyspepsia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Abdominal pain		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.270

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Gastrointestinal disorders	Abdominal pain	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.356
Gastrointestinal disorders	Abdominal pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Gastrointestinal disorders	Abdominal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Abdominal pain upper		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.460

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Gastrointesti nal disorders	Abdominal pain upper	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.460
Gastrointesti nal disorders	Abdominal pain upper	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Gastrointesti nal disorders	Abdominal pain upper	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Gastrointesti nal disorders	Constipation		1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.158 , I <sup>2</sup> =0%	P=0.317 , I <sup>2</sup> =0%							P=0.564
Gastrointesti nal disorders	Constipation	Mild	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.158 , I <sup>2</sup> =0%	P=0.317 , I <sup>2</sup> =0%	0.547 (0.035, 8.586)	0.547 (0.036, 8.353) 0.664	-0.013 (-0.075 - 0.049)	P=0.31 6, I <sup>2</sup> =53%	P=0.31 7, I <sup>2</sup> =13%	P=0.34 4, I <sup>2</sup> =0%	P=0.717

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Gastrointestinal disorders	Constipation	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Gastrointestinal disorders	Constipation	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Toothache		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.978
Gastrointestinal disorders	Toothache	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.978



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Gastrointestinal disorders	Toothache	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Toothache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Abdominal discomfort		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.601
Gastrointestinal disorders	Abdominal discomfort	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.601
Gastrointestinal disorders	Abdominal discomfort	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Gastrointestinal disorders	Abdominal discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Enteritis		1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.997
Gastrointestinal disorders	Enteritis	Mild	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	0.512 (0.030, 8.604)	0.524 (0.034, 7.979) 0.642	-0.013 (-0.074, 0.047)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.997
Gastrointestinal disorders	Enteritis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Gastrointestinal disorders	Enteritis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Gastrointestinal disorder		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.990
Gastrointestinal disorders	Gastrointestinal disorder	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.990
Gastrointestinal disorders	Gastrointestinal disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Gastrointestinal disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Gastrointestinal disorders	Gastrointestinal motility disorder		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.706
Gastrointestinal disorders	Gastrointestinal motility disorder	Mild	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706
Gastrointestinal disorders	Gastrointestinal motility disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Gastrointestinal motility disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Gastrointestinal disorders	Lip swelling		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.706
Gastrointestinal disorders	Lip swelling	Mild	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706
Gastrointestinal disorders	Lip swelling	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Lip swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Gastrointestinal disorders	Aphthous ulcer		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Gastrointestinal disorders	Aphthous ulcer	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Gastrointestinal disorders	Aphthous ulcer	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Aphthous ulcer	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Gastric disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Gastrointestinal disorders	Gastric disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Gastrointestinal disorders	Gastric disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Gastric disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Abdominal distension		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Gastrointestinal disorders	Abdominal distension	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Gastrointestinal disorders	Abdominal distension	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Abdominal distension	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Noninfective gingivitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
Gastrointestinal disorders	Noninfective gingivitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Gastrointestinal disorders	Noninfective gingivitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Gastrointestinal disorders	Noninfective gingivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
General disorders and administration site conditions			17.9% (10.5, 28.9)	13.9% (5.9, 29.3)	P=0.319, I <sup>2</sup> =0%	P=0.331, I <sup>2</sup> =0%							P=0.415

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
General disorders and administrati on site conditions		Mild	16.4% (9.3, 27.3)	11.1% (4.2, 26.1)	P=0.443 , I <sup>2</sup> =0%	P=0.535 , I <sup>2</sup> =0%	1.564 (0.457, 5.348)	1.466 (0.505, 4.255) 0.481	0.052 (-0.083 - 0.187)	P=0.90 2, I <sup>2</sup> =0%	P=0.88 4, I <sup>2</sup> =0%	P=0.96 6, I <sup>2</sup> =0%	P=0.264
General disorders and administrati on site conditions		Moderate	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331 , I <sup>2</sup> =0%	P=0.317 , I <sup>2</sup> =0%	0.512 (0.030, 8.604)	0.524 (0.034, 7.979) 0.642	-0.013 (-0.074 - 0.047)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.578
General disorders and administrati on site conditions		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Pyrexia		13.4% (7.1, 23.8)	11.1% (4.2, 26.1)	P=0.298, I <sup>2</sup> =0%	P=0.535, I <sup>2</sup> =0%							P=0.893
General disorders and administration site conditions	Pyrexia	Mild	11.9% (6.1, 22.1)	8.3% (2.7, 22.9)	P=0.431, I <sup>2</sup> =0%	P=0.835, I <sup>2</sup> =0%	1.482 (0.367, 5.987)	1.423 (0.402, 5.034) 0.584	0.035 (-0.084, 0.154)	P=0.801, I <sup>2</sup> =0%	P=0.810, I <sup>2</sup> =0%	P=0.714, I <sup>2</sup> =0%	P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Pyrexia	Moderate	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	0.512 (0.030, 8.604)	0.524 (0.034, 7.979) 0.642	-0.013 (-0.074, 0.047)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.393
General disorders and administration site conditions	Pyrexia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
General disorders and administrati on site conditions	Injection site pain		1.5% (0.2, 9.8)	0%	P=0.331 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.851
General disorders and administrati on site conditions	Injection site pain	Mild	1.5% (0.2, 9.8)	0%	P=0.331 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.851
General disorders and administrati on site conditions	Injection site pain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Injection site pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
General disorders and administration site conditions	Injection site pruritus		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.683

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Injection site pruritus	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.683
General disorders and administration site conditions	Injection site pruritus	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Injection site pruritus	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
General disorders and administration site conditions	Fatigue		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
General disorders and administration site conditions	Fatigue	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Fatigue	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
General disorders and administration site conditions	Fatigue	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
General disorders and administrati on site conditions	Injection site swelling		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.531
General disorders and administrati on site conditions	Injection site swelling	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.531

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Injection site swelling	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
General disorders and administration site conditions	Injection site swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
General disorders and administration site conditions	Injection site erythema		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.464

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Injection site erythema	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.464
General disorders and administration site conditions	Injection site erythema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Injection site erythema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
General disorders and administration site conditions	Injection site reaction		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.990

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Injection site reaction	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715
General disorders and administration site conditions	Injection site reaction	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
General disorders and administration site conditions	Injection site reaction	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
General disorders and administrati on site conditions	Gait disturbance		1.5% (0.2, 9.8)	0%	P=0.158 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.706
General disorders and administrati on site conditions	Gait disturbance	Mild	1.5% (0.2, 9.8)	0%	P=0.158 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.706

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
General disorders and administrati on site conditions	Gait disturbance	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
General disorders and administrati on site conditions	Gait disturbance	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Face oedema		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
General disorders and administration site conditions	Face oedema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
General disorders and administration site conditions	Face oedema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Face oedema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
General disorders and administration site conditions	Influenza like illness		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Influenza like illness	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
General disorders and administration site conditions	Influenza like illness	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.711

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Influenza like illness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
General disorders and administration site conditions	Injection site atrophy		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
General disorders and administration site conditions	Injection site atrophy	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
General disorders and administrati on site conditions	Injection site atrophy	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
General disorders and administrati on site conditions	Injection site atrophy	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
General disorders and administrati on site conditions	Injection site urticaria		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741
General disorders and administrati on site conditions	Injection site urticaria	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Injection site urticaria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
General disorders and administration site conditions	Injection site urticaria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
General disorders and administration site conditions	Medical device discomfort		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Medical device discomfort	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
General disorders and administration site conditions	Medical device discomfort	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Medical device discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
General disorders and administration site conditions	Vaccination site pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Vaccination site pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
General disorders and administration site conditions	Vaccination site pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
General disorders and administration site conditions	Vaccination site pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
General disorders and administrati on site conditions	Injection site haemorrhage		0%	2.8% (0.4, 17.3)	P=1.000 , I <sup>2</sup> =0%	P=0.317 , I <sup>2</sup> =0%							P=0.737
General disorders and administrati on site conditions	Injection site haemorrhage	Mild	0%	2.8% (0.4, 17.3)	P=1.000 , I <sup>2</sup> =0%	P=0.317 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.737

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Injection site haemorrhage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
General disorders and administration site conditions	Injection site haemorrhage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Injection site bruising		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
General disorders and administration site conditions	Injection site bruising	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
General disorders and administration site conditions	Injection site bruising	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Injection site bruising	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
General disorders and administration site conditions	Pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
General disorders and administration site conditions	Pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
General disorders and administrati on site conditions	Pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
General disorders and administrati on site conditions	Peripheral swelling		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.738
General disorders and administrati on site conditions	Peripheral swelling	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.738



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
General disorders and administration site conditions	Peripheral swelling	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
General disorders and administration site conditions	Peripheral swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Nervous system disorders			1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.158, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.958
Nervous system disorders		Mild	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.158, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	0.547 (0.035, 8.586)	0.547 (0.036, 8.353) 0.664	-0.013 (-0.075, 0.049)	P=0.316, I <sup>2</sup> =53%	P=0.317, I <sup>2</sup> =13%	P=0.344, I <sup>2</sup> =0%	P=0.992
Nervous system disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.898
Nervous system disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Nervous system disorders	Headache		1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.158, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.832

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Nervous system disorders	Headache	Mild	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.158, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	0.547 (0.035, 8.586)	0.547 (0.036, 8.353) 0.664	-0.013 (-0.075 - 0.049)	P=0.316, I <sup>2</sup> =53%	P=0.317, I <sup>2</sup> =13%	P=0.344, I <sup>2</sup> =0%	P=0.847
Nervous system disorders	Headache	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.898
Nervous system disorders	Headache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Nervous system disorders	Dizziness		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.694

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Nervous system disorders	Dizziness	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.694
Nervous system disorders	Dizziness	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Nervous system disorders	Dizziness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Nervous system disorders	Post-traumatic headache		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Nervous system disorders	Post-traumatic headache	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Nervous system disorders	Post-traumatic headache	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Nervous system disorders	Post-traumatic headache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Nervous system disorders	Migraine		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Nervous system disorders	Migraine	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Nervous system disorders	Migraine	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Nervous system disorders	Migraine	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Nervous system disorders	Tremor		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Nervous system disorders	Tremor	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Nervous system disorders	Tremor	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Nervous system disorders	Tremor	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications			6.0% (2.3, 14.9)	5.6% (1.4, 19.7)	P=0.594, I <sup>2</sup> =0%	P=0.153, I <sup>2</sup> =0%							P=0.713
Injury, poisoning and procedural complications		Mild	3.0% (0.7, 11.2)	5.6% (1.4, 19.7)	P=0.711, I <sup>2</sup> =0%	P=0.153, I <sup>2</sup> =0%	0.524 (0.072, 3.808)	0.535 (0.079, 3.615) 0.521	-0.026 (-0.112, 0.060)	P=0.341, I <sup>2</sup> =0%	P=0.344, I <sup>2</sup> =0%	P=0.320, I <sup>2</sup> =0%	P=0.521

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Injury, poisoning and procedural complications		Moderate	3.0% (0.7, 11.2)	0%	P=0.711, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.011 - 0.071)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.676, I <sup>2</sup> =0%	P=0.953
Injury, poisoning and procedural complications		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Head injury		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.307



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Injury, poisoning and procedural complications	Head injury	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.307
Injury, poisoning and procedural complications	Head injury	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Head injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Injury, poisoning and procedural complications	Contusion		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.977
Injury, poisoning and procedural complications	Contusion	Mild	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Injury, poisoning and procedural complications	Contusion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Injury, poisoning and procedural complications	Contusion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Animal bite		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Injury, poisoning and procedural complications	Animal bite	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Animal bite	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Animal bite	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Injury, poisoning and procedural complications	Arthropod bite		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Arthropod bite	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Arthropod bite	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Injury, poisoning and procedural complications	Arthropod bite	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Ligament sprain		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.556
Injury, poisoning and procedural complications	Ligament sprain	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.556

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Injury, poisoning and procedural complications	Ligament sprain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Ligament sprain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Injury, poisoning and procedural complications	Post-traumatic pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Post-traumatic pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Post-traumatic pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Injury, poisoning and procedural complications	Post-traumatic pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Skin laceration		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.990
Injury, poisoning and procedural complications	Skin laceration	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Injury, poisoning and procedural complications	Skin laceration	Moderate	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715
Injury, poisoning and procedural complications	Skin laceration	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Burns second degree		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.706

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Injury, poisoning and procedural complications	Burns second degree	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Burns second degree	Moderate	1.5% (0.2, 9.8)	0%	P=0.158 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.706
Injury, poisoning and procedural complications	Burns second degree	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Injury, poisoning and procedural complications	Fall		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.706
Injury, poisoning and procedural complications	Fall	Mild	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Injury, poisoning and procedural complications	Fall	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Fall	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Ankle fracture		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Injury, poisoning and procedural complications	Ankle fracture	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Ankle fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741
Injury, poisoning and procedural complications	Ankle fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Injury, poisoning and procedural complications	Burns first degree		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Injury, poisoning and procedural complications	Burns first degree	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Injury, poisoning and procedural complications	Burns first degree	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Injury, poisoning and procedural complications	Burns first degree	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Concussion		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Injury, poisoning and procedural complications	Concussion	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Injury, poisoning and procedural complications	Concussion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Concussion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Injury, poisoning and procedural complications	Face injury		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Injury, poisoning and procedural complications	Face injury	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Face injury	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Injury, poisoning and procedural complications	Face injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Laceration		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Injury, poisoning and procedural complications	Laceration	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Injury, poisoning and procedural complications	Laceration	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Laceration	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Meniscus injury		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Injury, poisoning and procedural complications	Meniscus injury	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Meniscus injury	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.711
Injury, poisoning and procedural complications	Meniscus injury	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Injury, poisoning and procedural complications	Muscle strain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Injury, poisoning and procedural complications	Muscle strain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Injury, poisoning and procedural complications	Muscle strain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Injury, poisoning and procedural complications	Muscle strain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Radius fracture		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Injury, poisoning and procedural complications	Radius fracture	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741
Injury, poisoning and procedural complications	Radius fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Radius fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Injury, poisoning and procedural complications	Thermal burn		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Injury, poisoning and procedural complications	Thermal burn	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Injury, poisoning and procedural complications	Thermal burn	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Injury, poisoning and procedural complications	Thermal burn	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Upper limb fracture		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741
Injury, poisoning and procedural complications	Upper limb fracture	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Injury, poisoning and procedural complications	Upper limb fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Upper limb fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Injury, poisoning and procedural complications	Wrist fracture		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741
Injury, poisoning and procedural complications	Wrist fracture	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741
Injury, poisoning and procedural complications	Wrist fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Injury, poisoning and procedural complications	Wrist fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Animal scratch		0%	2.8% (0.4, 17.3)	P=1.000 , I <sup>2</sup> =0%	P=0.317 , I <sup>2</sup> =0%							P=0.737
Injury, poisoning and procedural complications	Animal scratch	Mild	0%	2.8% (0.4, 17.3)	P=1.000 , I <sup>2</sup> =0%	P=0.317 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.737

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Injury, poisoning and procedural complications	Animal scratch	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Animal scratch	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Eye injury		1.5% (0.2, 9.8)	0%	P=0.331 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.715

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Injury, poisoning and procedural complications	Eye injury	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715
Injury, poisoning and procedural complications	Eye injury	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Eye injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Injury, poisoning and procedural complications	Joint injury		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Injury, poisoning and procedural complications	Joint injury	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Injury, poisoning and procedural complications	Joint injury	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Injury, poisoning and procedural complications	Joint injury	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders			11.9% (6.1, 22.1)	2.8% (0.4, 17.3)	P=0.991 , I <sup>2</sup> =0%	P=0.164 , I <sup>2</sup> =0%							P=0.418
Skin and subcutaneous tissue disorders		Mild	11.9% (6.1, 22.1)	2.8% (0.4, 17.3)	P=0.991 , I <sup>2</sup> =0%	P=0.164 , I <sup>2</sup> =0%	4.820 (0.568, 40.929)	4.361 (0.558, 34.072) 0.16	0.092 (-0.002 - 0.186)	P=0.393, I <sup>2</sup> =0%	P=0.375, I <sup>2</sup> =0%	P=0.605, I <sup>2</sup> =0%	P=0.683

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Skin and subcutaneous tissue disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.750
Skin and subcutaneous tissue disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Rash		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.672

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Skin and subcutaneous tissue disorders	Rash	Mild	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.672
Skin and subcutaneous tissue disorders	Rash	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Rash	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Urticaria		3.0% (0.7, 11.2)	0%	P=0.168, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.723

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Skin and subcutaneous tissue disorders	Urticaria	Mild	3.0% (0.7, 11.2)	0%	P=0.168, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.029 (-0.011 - 0.070)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.968
Skin and subcutaneous tissue disorders	Urticaria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Skin and subcutaneous tissue disorders	Urticaria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Skin and subcutaneous tissue disorders	Dermatitis allergic		1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%							P=0.984
Skin and subcutaneous tissue disorders	Dermatitis allergic	Mild	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%	0.536 (0.033, 8.736)	0.536 (0.032, 8.984) 0.665	-0.013 (-0.074 - 0.048)	P=0.344, I <sup>2</sup> =0%	P=0.350, I <sup>2</sup> =0%	P=0.299, I <sup>2</sup> =741%	P=0.984
Skin and subcutaneous tissue disorders	Dermatitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Dermatitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Skin and subcutaneous tissue disorders	Eczema		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808
Skin and subcutaneous tissue disorders	Eczema	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.990
Skin and subcutaneous tissue disorders	Eczema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Skin and subcutaneous tissue disorders	Eczema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Dermatitis contact		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Skin and subcutaneous tissue disorders	Dermatitis contact	Mild	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.980
Skin and subcutaneous tissue disorders	Dermatitis contact	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Skin and subcutaneous tissue disorders	Dermatitis contact	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Urticaria papular		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.990
Skin and subcutaneous tissue disorders	Urticaria papular	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.990



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Skin and subcutaneous tissue disorders	Urticaria papular	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Urticaria papular	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Cafe au lait spots		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.706
Skin and subcutaneous tissue disorders	Cafe au lait spots	Mild	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Skin and subcutaneous tissue disorders	Cafe au lait spots	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Cafe au lait spots	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Keratosis pilaris		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.706

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Skin and subcutaneous tissue disorders	Keratosis pilaris	Mild	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706
Skin and subcutaneous tissue disorders	Keratosis pilaris	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Keratosis pilaris	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Pityriasis alba		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.706

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Skin and subcutaneous tissue disorders	Pityriasis alba	Mild	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706
Skin and subcutaneous tissue disorders	Pityriasis alba	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Pityriasis alba	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Skin and subcutaneous tissue disorders	Petechiae		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Skin and subcutaneous tissue disorders	Petechiae	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Skin and subcutaneous tissue disorders	Petechiae	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Petechiae	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Skin and subcutaneous tissue disorders	Rash erythematous		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Skin and subcutaneous tissue disorders	Rash erythematous	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Skin and subcutaneous tissue disorders	Rash erythematous	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Skin and subcutaneous tissue disorders	Rash erythematous	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Rash pruritic		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Skin and subcutaneous tissue disorders	Rash pruritic	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Rash pruritic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Skin and subcutaneous tissue disorders	Rash pruritic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Dermatitis		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.715
Skin and subcutaneous tissue disorders	Dermatitis	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Skin and subcutaneous tissue disorders	Dermatitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Dermatitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Urticaria chronic		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.715
Skin and subcutaneous tissue disorders	Urticaria chronic	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Skin and subcutaneous tissue disorders	Urticaria chronic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Urticaria chronic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Dyshidrotic eczema		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Eye disorders			4.5% (1.5, 13.0)	5.6% (1.4, 19.7)	P=0.883, I <sup>2</sup> =0%	P=0.153, I <sup>2</sup> =0%							P=0.387

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Eye disorders		Mild	4.5% (1.5, 13.0)	5.6% (1.4, 19.7)	P=0.883, I <sup>2</sup> =0%	P=0.153, I <sup>2</sup> =0%	0.787 (0.126, 4.929)	0.797 (0.141, 4.497) 0.797	-0.011 (-0.101, 0.078)	P=0.512, I <sup>2</sup> =0%	P=0.515, I <sup>2</sup> =0%	P=0.474, I <sup>2</sup> =0%	P=0.430
Eye disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Eye disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Eye disorders	Refraction disorder		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.360

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Eye disorders	Refraction disorder	Mild	0%	2.8% (0.4, 17.3)	P=1.000 , I <sup>2</sup> =0%	P=0.317 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.360
Eye disorders	Refraction disorder	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Eye disorders	Refraction disorder	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Eye disorders	Eye swelling		1.5% (0.2, 9.8)	0%	P=0.158 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Eye disorders	Eye swelling	Mild	1.5% (0.2, 9.8)	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706
Eye disorders	Eye swelling	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Eye disorders	Eye swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Eye disorders	Conjunctivit is allergic		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.987
Eye disorders	Conjunctivit is allergic	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.987

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Eye disorders	Conjunctivitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Eye disorders	Conjunctivitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Eye disorders	Myopia		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.447
Eye disorders	Myopia	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.447

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Eye disorders	Myopia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Eye disorders	Myopia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Eye disorders	Strabismus		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Strabismus	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Strabismus	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Eye disorders	Strabismus	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Eye disorders	Papilloedema		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.982
Eye disorders	Papilloedema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.982
Eye disorders	Papilloedema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Eye disorders	Papilloedema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Eye disorders	Astigmatism		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Eye disorders	Astigmatism	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Eye disorders	Astigmatism	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Eye disorders	Astigmatism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Eye disorders	Eye haemorrhage		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Eye disorders	Eye haemorrhage	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Eye disorders	Eye haemorrhage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Eye disorders	Eye haemorrhage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Eye disorders	Hypermetropia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Eye disorders	Hypermetropia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Eye disorders	Hypermetropia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Eye disorders	Hypermetropia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Eye disorders	Vernal keratoconjunctivitis		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.737

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Eye disorders	Vernal keratoconjunctivitis	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.737
Eye disorders	Vernal keratoconjunctivitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Eye disorders	Vernal keratoconjunctivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Eye disorders	Corneal epithelium defect		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Eye disorders	Corneal epithelium defect	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Eye disorders	Corneal epithelium defect	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Eye disorders	Corneal epithelium defect	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Eye disorders	Eye pain		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.738
Eye disorders	Eye pain	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.738

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Eye disorders	Eye pain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Eye disorders	Eye pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Eye disorders	Vitreous opacities		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.738
Eye disorders	Vitreous opacities	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.738
Eye disorders	Vitreous opacities	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Eye disorders	Vitreous opacities	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Eye disorders	Xerophthalmia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
Eye disorders	Xerophthalmia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
Eye disorders	Xerophthalmia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Eye disorders	Xerophthalmia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Musculoskeletal and connective tissue disorders			3.0% (0.7, 11.2)	5.6% (1.4, 19.7)	P=0.711, I <sup>2</sup> =0%	P=0.046, I <sup>2</sup> =0%							P=0.351
Musculoskeletal and connective tissue disorders		Mild	3.0% (0.7, 11.2)	5.6% (1.4, 19.7)	P=0.711, I <sup>2</sup> =0%	P=0.046, I <sup>2</sup> =0%	0.529 (0.070, 3.975)	0.548 (0.080, 3.739) 0.539	-0.025 (-0.109, 0.060)	P=0.369, I <sup>2</sup> =0%	P=0.381, I <sup>2</sup> =0%	P=0.231, I <sup>2</sup> =3027%	P=0.459

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Musculoskeletal and connective tissue disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.601
Musculoskeletal and connective tissue disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Musculoskeletal and connective tissue disorders	Pain in extremity		1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%							P=0.771

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Musculoskeletal and connective tissue disorders	Pain in extremity	Mild	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%	0.536 (0.033, 8.736)	0.536 (0.032, 8.984) 0.665	-0.013 (-0.074, 0.048)	P=0.344, I <sup>2</sup> =0%	P=0.350, I <sup>2</sup> =0%	P=0.299, I <sup>2</sup> =741%	P=0.899
Musculoskeletal and connective tissue disorders	Pain in extremity	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Musculoskeletal and connective tissue disorders	Pain in extremity	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Musculoskeletal and connective tissue disorders	Arthralgia		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.628
Musculoskeletal and connective tissue disorders	Arthralgia	Mild	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.628
Musculoskeletal and connective tissue disorders	Arthralgia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Musculoskeletal and connective tissue disorders	Arthralgia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Musculoskeletal and connective tissue disorders	Musculoskeletal pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.601
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Musculoskeletal and connective tissue disorders	Neck pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Musculoskeletal and connective tissue disorders	Neck pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Musculoskeletal and connective tissue disorders	Neck pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Musculoskeletal and connective tissue disorders	Neck pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Musculoskeletal and connective tissue disorders	Synovial cyst		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%							P=0.740
Musculoskeletal and connective tissue disorders	Synovial cyst	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.081 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.740



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Musculoskeletal and connective tissue disorders	Synovial cyst	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Musculoskeletal and connective tissue disorders	Synovial cyst	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Musculoskeletal and connective tissue disorders	Arthritis reactive		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Musculoskeletal and connective tissue disorders	Arthritis reactive	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Musculoskeletal and connective tissue disorders	Arthritis reactive	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Musculoskeletal and connective tissue disorders	Arthritis reactive	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Musculoskeletal and connective tissue disorders	Back pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Musculoskeletal and connective tissue disorders	Back pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Musculoskeletal and connective tissue disorders	Back pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Musculoskeletal and connective tissue disorders	Back pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Musculoskeletal and connective tissue disorders	Neck mass		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Musculoskeletal and connective tissue disorders	Neck mass	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Musculoskeletal and connective tissue disorders	Neck mass	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Musculoskeletal and connective tissue disorders	Neck mass	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Musculoskeletal and connective tissue disorders	Pain in jaw		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Musculoskeletal and connective tissue disorders	Pain in jaw	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Musculoskeletal and connective tissue disorders	Pain in jaw	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Musculoskeletal and connective tissue disorders	Pain in jaw	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Musculoskeletal and connective tissue disorders	Scoliosis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Musculoskeletal and connective tissue disorders	Scoliosis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Musculoskeletal and connective tissue disorders	Scoliosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Musculoskeletal and connective tissue disorders	Scoliosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Metabolism and nutrition disorders			10.4% (5.1, 20.3)	2.8% (0.4, 17.3)	P=0.008, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.102



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Metabolism and nutrition disorders		Mild	10.4% (5.1, 20.3)	2.8% (0.4, 17.3)	P=0.008, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	4.200 (0.482, 36.565)	3.667 (0.481, 27.941) 0.21	0.075 (-0.014 - 0.164)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.102
Metabolism and nutrition disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Metabolism and nutrition disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Metabolism and nutrition disorders	Hypertriglyceridaemia		4.5% (1.5, 13.0)	0%	P=0.089, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.631
Metabolism and nutrition disorders	Hypertriglyceridaemia	Mild	4.5% (1.5, 13.0)	0%	P=0.089, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.044 (-0.005 - 0.093)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.631
Metabolism and nutrition disorders	Hypertriglyceridaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Metabolism and nutrition disorders	Hypertriglyceridaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Metabolism and nutrition disorders	Hypercholesterolaemia		3.0% (0.7, 11.2)	2.8% (0.4, 17.3)	P=0.168, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.482
Metabolism and nutrition disorders	Hypercholesterolaemia	Mild	3.0% (0.7, 11.2)	2.8% (0.4, 17.3)	P=0.168, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	1.050 (0.090, 12.264)	1.048 (0.100, 10.923)	0.001 (-0.065 - 0.068)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.482
Metabolism and nutrition disorders	Hypercholesterolaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Metabolism and nutrition disorders	Hypercholes terolaemia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Metabolism and nutrition disorders	Decreased appetite		3.0% (0.7, 11.2)	0%	P=0.168 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.332
Metabolism and nutrition disorders	Decreased appetite	Mild	3.0% (0.7, 11.2)	0%	P=0.168 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.029 (-0.011 - 0.070)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.332
Metabolism and nutrition disorders	Decreased appetite	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Metabolism and nutrition disorders	Decreased appetite	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Metabolism and nutrition disorders	Hyperuricaemia		1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331 , I <sup>2</sup> =0%	P=0.317 , I <sup>2</sup> =0%							P=0.699
Metabolism and nutrition disorders	Hyperuricaemia	Mild	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331 , I <sup>2</sup> =0%	P=0.317 , I <sup>2</sup> =0%	0.512 (0.030, 8.604)	0.524 (0.034, 7.979) 0.642	-0.013 (-0.074 - 0.047)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.699

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Metabolism and nutrition disorders	Hyperuricaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Metabolism and nutrition disorders	Hyperuricaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Metabolism and nutrition disorders	Polydipsia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Metabolism and nutrition disorders	Polydipsia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Metabolism and nutrition disorders	Polydipsia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Metabolism and nutrition disorders	Polydipsia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Metabolism and nutrition disorders	Calcium deficiency		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Metabolism and nutrition disorders	Calcium deficiency	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
Metabolism and nutrition disorders	Calcium deficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Metabolism and nutrition disorders	Calcium deficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Metabolism and nutrition disorders	Hyperglycaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Metabolism and nutrition disorders	Hyperglycaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
Metabolism and nutrition disorders	Hyperglycaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Metabolism and nutrition disorders	Hyperglycaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Metabolism and nutrition disorders	Hyperlipidaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
Metabolism and nutrition disorders	Hyperlipidaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
Metabolism and nutrition disorders	Hyperlipidaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Metabolism and nutrition disorders	Hyperlipidaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Endocrine disorders			1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.158, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%							P=0.709
Endocrine disorders		Mild	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.158, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%	0.542 (0.031, 9.390)	0.560 (0.038, 8.279) 0.673	-0.012 (-0.072, 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.853
Endocrine disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.601
Endocrine disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Endocrine disorders	Secondary hypothyroidism		1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.158, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%							P=0.504
Endocrine disorders	Secondary hypothyroidism	Mild	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.158, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%	0.542 (0.031, 9.390)	0.560 (0.038, 8.279)	-0.012 (-0.072, 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.586
Endocrine disorders	Secondary hypothyroidism	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Endocrine disorders	Secondary hypothyroidism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Endocrine disorders	Hypothyroidism		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.868
Endocrine disorders	Hypothyroidism	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.868
Endocrine disorders	Hypothyroidism	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Endocrine disorders	Hypothyroidism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Endocrine disorders	Diabetes insipidus		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Endocrine disorders	Diabetes insipidus	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Endocrine disorders	Diabetes insipidus	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Endocrine disorders	Diabetes insipidus	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Endocrine disorders	Secondary adrenocortical insufficiency		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Endocrine disorders	Secondary adrenocortical insufficiency	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Endocrine disorders	Secondary adrenocortical insufficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Endocrine disorders	Secondary adrenocortical insufficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Endocrine disorders	Adrenal insufficiency		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Endocrine disorders	Adrenal insufficiency	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Endocrine disorders	Adrenal insufficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Endocrine disorders	Adrenal insufficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Endocrine disorders	Precocious puberty		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
Endocrine disorders	Precocious puberty	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
Endocrine disorders	Precocious puberty	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Endocrine disorders	Precocious puberty	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Blood and lymphatic system disorders			9.0% (4.1, 18.5)	2.8% (0.4, 17.3)	P=0.507, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.594
Blood and lymphatic system disorders		Mild	7.5% (3.1, 16.7)	2.8% (0.4, 17.3)	P=0.898, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	2.794 (0.316, 24.734)	2.665 (0.327, 21.730) 0.36	0.047 (-0.036 - 0.130)	P=0.641, I <sup>2</sup> =0%	P=0.636, I <sup>2</sup> =0%	P=0.682, I <sup>2</sup> =0%	P=0.489
Blood and lymphatic system disorders		Moderate	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.817

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Blood and lymphatic system disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Blood and lymphatic system disorders	Anaemia		1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.158 , I <sup>2</sup> =0%	P=0.317 , I <sup>2</sup> =0%							P=0.479
Blood and lymphatic system disorders	Anaemia	Mild	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.158 , I <sup>2</sup> =0%	P=0.317 , I <sup>2</sup> =0%	0.547 (0.035, 8.586)	0.547 (0.036, 8.353)	-0.013 (-0.075 - 0.049)	P=0.316, I <sup>2</sup> =53%	P=0.317, I <sup>2</sup> =13%	P=0.344, I <sup>2</sup> =0%	P=0.479

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Blood and lymphatic system disorders	Anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Blood and lymphatic system disorders	Anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Blood and lymphatic system disorders	Iron deficiency anaemia		3.0% (0.7, 11.2)	0%	P=0.044, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.817
Blood and lymphatic system disorders	Iron deficiency anaemia	Mild	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.977

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Blood and lymphatic system disorders	Iron deficiency anaemia	Moderate	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706
Blood and lymphatic system disorders	Iron deficiency anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Blood and lymphatic system disorders	Lymphadenopathy		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Blood and lymphatic system disorders	Lymphadenopathy	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Blood and lymphatic system disorders	Lymphadenopathy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Blood and lymphatic system disorders	Lymphadenopathy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Blood and lymphatic system disorders	Neutropenia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.601

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Blood and lymphatic system disorders	Neutropenia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.601
Blood and lymphatic system disorders	Neutropenia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Blood and lymphatic system disorders	Neutropenia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Blood and lymphatic system disorders	Lymphadenitis		3.0% (0.7, 11.2)	0%	P=0.168, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.578
Blood and lymphatic system disorders	Lymphadenitis	Mild	3.0% (0.7, 11.2)	0%	P=0.168, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.029 (-0.011 - 0.070)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.578
Blood and lymphatic system disorders	Lymphadenitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Blood and lymphatic system disorders	Lymphadenitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Blood and lymphatic system disorders	Granulocytopenia		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.990
Blood and lymphatic system disorders	Granulocytopenia	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.990
Blood and lymphatic system disorders	Granulocytopenia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Blood and lymphatic system disorders	Granulocytopenia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Blood and lymphatic system disorders	Hypochromic anaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Blood and lymphatic system disorders	Hypochromic anaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Blood and lymphatic system disorders	Hypochromic anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Blood and lymphatic system disorders	Hypochromic anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Blood and lymphatic system disorders	Thymus disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Blood and lymphatic system disorders	Thymus disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Blood and lymphatic system disorders	Thymus disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Blood and lymphatic system disorders	Thymus disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Immune system disorders			0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.199
Immune system disorders		Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.233

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Immune system disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Immune system disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Immune system disorders	Seasonal allergy		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.552
Immune system disorders	Seasonal allergy	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.552
Immune system disorders	Seasonal allergy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Immune system disorders	Seasonal allergy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Immune system disorders	Hypersensitivity		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.714
Immune system disorders	Hypersensitivity	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.987
Immune system disorders	Hypersensitivity	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Immune system disorders	Hypersensitivity	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Immune system disorders	Allergy to animal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.601
Immune system disorders	Allergy to animal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.601
Immune system disorders	Allergy to animal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Immune system disorders	Allergy to animal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Immune system disorders	Food allergy		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Immune system disorders	Food allergy	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Immune system disorders	Food allergy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Immune system disorders	Food allergy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Reproductive system and breast disorders			3.0% (0.7, 11.2)	2.8% (0.4, 17.3)	P=0.168, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%							P=0.900
Reproductive system and breast disorders		Mild	3.0% (0.7, 11.2)	2.8% (0.4, 17.3)	P=0.168, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%	1.073 (0.096, 12.043)	1.073 (0.094, 12.267)	0.002 (-0.066 - 0.070)	P=0.215, I <sup>2</sup> =349%	P=0.219, I <sup>2</sup> =338%	P=0.212, I <sup>2</sup> =357%	P=0.900
Reproductive system and breast disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Reproductive system and breast disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Reproductive system and breast disorders	Penile adhesion		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%							P=0.982
Reproductive system and breast disorders	Penile adhesion	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.081 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.982
Reproductive system and breast disorders	Penile adhesion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Reproductive system and breast disorders	Penile adhesion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Reproductive system and breast disorders	Gynaecomastia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.598
Reproductive system and breast disorders	Gynaecomastia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.598
Reproductive system and breast disorders	Gynaecomastia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Reproductiv e system and breast disorders	Gynaecomasia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Reproductiv e system and breast disorders	Genital discomfort		0%	2.8% (0.4, 17.3)	P=1.000 , I <sup>2</sup> =0%	P=0.164 , I <sup>2</sup> =0%							P=0.740
Reproductiv e system and breast disorders	Genital discomfort	Mild	0%	2.8% (0.4, 17.3)	P=1.000 , I <sup>2</sup> =0%	P=0.164 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.027 (-0.081 - 0.026)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.740

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Reproductiv e system and breast disorders	Genital discomfort	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Reproductiv e system and breast disorders	Genital discomfort	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Reproductiv e system and breast disorders	Balanoposth itis		1.5% (0.2, 9.8)	0%	P=0.331 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.715
Reproductiv e system and breast disorders	Balanoposth itis	Mild	1.5% (0.2, 9.8)	0%	P=0.331 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Reproductiv e system and breast disorders	Balanoposth itis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Reproductiv e system and breast disorders	Balanoposth itis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Reproductiv e system and breast disorders	Pelvic fluid collection		1.5% (0.2, 9.8)	0%	P=0.331 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.715

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Reproductive system and breast disorders	Pelvic fluid collection	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715
Reproductive system and breast disorders	Pelvic fluid collection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Reproductive system and breast disorders	Pelvic fluid collection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Reproductive system and breast disorders	Testicular appendage torsion		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Reproductive system and breast disorders	Testicular appendage torsion	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Reproductive system and breast disorders	Testicular appendage torsion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Reproductive system and breast disorders	Testicular appendage torsion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Ear and labyrinth disorders			3.0% (0.7, 11.2)	2.8% (0.4, 17.3)	P=0.711, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.639
Ear and labyrinth disorders		Mild	3.0% (0.7, 11.2)	2.8% (0.4, 17.3)	P=0.711, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	1.073 (0.095, 12.052)	1.071 (0.102, 11.282)	0.002 (-0.066 - 0.070)	P=0.551, I <sup>2</sup> =0%	P=0.551, I <sup>2</sup> =0%	P=0.560, I <sup>2</sup> =0%	P=0.639
Ear and labyrinth disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Ear and labyrinth disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Ear and labyrinth disorders	Ear pain		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.759



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Ear and labyrinth disorders	Ear pain	Mild	1.5% (0.2, 9.8)	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.759
Ear and labyrinth disorders	Ear pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Ear and labyrinth disorders	Ear pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Ear and labyrinth disorders	Cerumen impaction		0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%							P=0.737

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Ear and labyrinth disorders	Cerumen impaction	Mild	0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.028 (-0.082 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.737
Ear and labyrinth disorders	Cerumen impaction	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Ear and labyrinth disorders	Cerumen impaction	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Ear and labyrinth disorders	Motion sickness		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.715

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Ear and labyrinth disorders	Motion sickness	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715
Ear and labyrinth disorders	Motion sickness	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Ear and labyrinth disorders	Motion sickness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Psychiatric disorders			3.0% (0.7, 11.2)	0%	P=0.044, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.720

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Psychiatric disorders		Mild	3.0% (0.7, 11.2)	0%	P=0.044, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.031 (-0.011 - 0.072)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.519
Psychiatric disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Psychiatric disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Psychiatric disorders	Attention deficit/hyper activity disorder		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.439
Psychiatric disorders	Attention deficit/hyper activity disorder	Mild	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.439

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Psychiatric disorders	Attention deficit/hyperactivity disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Psychiatric disorders	Attention deficit/hyperactivity disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Psychiatric disorders	Enuresis		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.706
Psychiatric disorders	Enuresis	Mild	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Psychiatric disorders	Enuresis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Psychiatric disorders	Enuresis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Psychiatric disorders	Affect lability		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Psychiatric disorders	Affect lability	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Psychiatric disorders	Affect lability	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Psychiatric disorders	Affect lability	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Psychiatric disorders	Depressive symptom		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Psychiatric disorders	Depressive symptom	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Psychiatric disorders	Depressive symptom	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Psychiatric disorders	Depressive symptom	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.894



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Mild	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.894
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.792

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.792

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma		1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.706
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Mild	1.5% (0.2, 9.8)	0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Cardiac disorders			1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.684
Cardiac disorders		Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.808
Cardiac disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Cardiac disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Cardiac disorders	Sinoatrial block		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Cardiac disorders	Sinoatrial block	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Cardiac disorders	Sinoatrial block	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Cardiac disorders	Sinoatrial block	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Cardiac disorders	Sinus tachycardia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Cardiac disorders	Sinus tachycardia	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Cardiac disorders	Sinus tachycardia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741
Cardiac disorders	Sinus tachycardia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Cardiac disorders	Tachycardia		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741
Cardiac disorders	Tachycardia	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.741

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Cardiac disorders	Tachycardia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Cardiac disorders	Tachycardia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Cardiac disorders	Myocarditis		1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.715
Cardiac disorders	Myocarditis	Mild	1.5% (0.2, 9.8)	0%	P=0.331, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.014 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Cardiac disorders	Myocarditis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Cardiac disorders	Myocarditis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Cardiac disorders	Wandering pacemaker		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Cardiac disorders	Wandering pacemaker	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Cardiac disorders	Wandering pacemaker	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Cardiac disorders	Wandering pacemaker	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Renal and urinary disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.872
Renal and urinary disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.872
Renal and urinary disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Renal and urinary disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Renal and urinary disorders	Pollakiuria		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Renal and urinary disorders	Pollakiuria	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Renal and urinary disorders	Pollakiuria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Renal and urinary disorders	Pollakiuria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Renal and urinary disorders	Polyuria		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Renal and urinary disorders	Polyuria	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.741
Renal and urinary disorders	Polyuria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Renal and urinary disorders	Polyuria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Renal and urinary disorders	Nocturia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Renal and urinary disorders	Nocturia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.712
Renal and urinary disorders	Nocturia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Renal and urinary disorders	Nocturia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Vascular disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.457

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Vascular disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.457
Vascular disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Vascular disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Vascular disorders	Hypotension		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.601
Vascular disorders	Hypotension	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.601



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Vascular disorders	Hypotension	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Vascular disorders	Hypotension	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Vascular disorders	Cyanosis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Vascular disorders	Cyanosis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Vascular disorders	Cyanosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Vascular disorders	Cyanosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Congenital, familial and genetic disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.598
Congenital, familial and genetic disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.598

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Congenital, familial and genetic disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Congenital, familial and genetic disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Congenital, familial and genetic disorders	Buried penis syndrome		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Congenital, familial and genetic disorders	Buried penis syndrome	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age < 6 years													
Congenital, familial and genetic disorders	Buried penis syndrome	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Congenital, familial and genetic disorders	Buried penis syndrome	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.986
Congenital, familial and genetic disorders	Supernumerary teeth		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.738

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Congenital, familial and genetic disorders	Supernumerary teeth	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.738
Congenital, familial and genetic disorders	Supernumerary teeth	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Congenital, familial and genetic disorders	Supernumerary teeth	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Hepatobiliary disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Hepatobiliary disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Hepatobiliary disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Hepatobiliary disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Hepatobiliary disorders	Hepatomegaly		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711
Hepatobiliary disorders	Hepatomegaly	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.711

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years													
Hepatobiliary disorders	Hepatomegaly	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Hepatobiliary disorders	Hepatomegaly	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Any adverse event			85.5% (78.6, 90.5)	79.5% (68.7, 87.2)	P=0.000 , I <sup>2</sup> =86.9%	P=0.007 , I <sup>2</sup> =82%							
Any adverse event		Mild	67.4% (59.1, 74.7)	57.5% (46.0, 68.3)	P=0.000 , I <sup>2</sup> =94.7%	P=0.000 , I <sup>2</sup> =94%	1.725 (0.888, 3.350)	1.175 (0.956, 1.443) 0.125	0.100 (-0.022 - 0.223)	P=0.624, I <sup>2</sup> =0%	P=0.069, I <sup>2</sup> =6980%	P=0.233, I <sup>2</sup> =2976%	
Any adverse event		Moderate	16.7% (11.3, 23.8)	21.9% (13.9, 32.8)	P=0.006 , I <sup>2</sup> =83.6%	P=0.004 , I <sup>2</sup> =84%	0.690 (0.329, 1.446)	0.757 (0.437, 1.311) 0.32	-0.053 (-0.163 - 0.056)	P=0.582, I <sup>2</sup> =0%	P=0.645, I <sup>2</sup> =0%	P=0.248, I <sup>2</sup> =2504%	



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Any adverse event		Severe	1.4% (0.4, 5.6)	0%	P=0.819, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.005 - 0.034)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.706, I <sup>2</sup> =0%	
Infections and infestations			50.0% (41.7, 58.3)	53.4% (42.0, 64.5)	P=0.730, I <sup>2</sup> =0%	P=0.790, I <sup>2</sup> =0%							
Infections and infestations		Mild	39.1% (31.4, 47.5)	41.1% (30.4, 52.7)	P=0.244, I <sup>2</sup> =26.3 %	P=0.277, I <sup>2</sup> =15%	0.922 (0.515, 1.650)	0.953 (0.677, 1.343) 0.784	-0.019 (-0.157 - 0.119)	P=0.852, I <sup>2</sup> =0%	P=0.871, I <sup>2</sup> =0%	P=0.843, I <sup>2</sup> =0%	
Infections and infestations		Moderate	9.4% (5.5, 15.5)	12.3% (6.5, 22.0)	P=0.004, I <sup>2</sup> =79.1 %	P=0.029, I <sup>2</sup> =69%	0.722 (0.285, 1.827)	0.760 (0.349, 1.655) 0.489	-0.030 (-0.117 - 0.058)	P=0.815, I <sup>2</sup> =0%	P=0.790, I <sup>2</sup> =0%	P=0.665, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations		Severe	1.4% (0.4, 5.6)	0%	P=0.819, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.005 - 0.034)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.706, I <sup>2</sup> =0%	
Infections and infestations	Upper respiratory tract infection		18.1% (12.5, 25.4)	21.9% (13.9, 32.8)	P=0.000, I <sup>2</sup> =94%	P=0.016, I <sup>2</sup> =81%							
Infections and infestations	Upper respiratory tract infection	Mild	18.1% (12.5, 25.4)	17.8% (10.6, 28.3)	P=0.000, I <sup>2</sup> =94%	P=0.005, I <sup>2</sup> =85%	1.034 (0.468, 2.285)	1.024 (0.581, 1.805) 0.933	0.004 (-0.097 - 0.106)	P=0.546, I <sup>2</sup> =0%	P=0.554, I <sup>2</sup> =0%	P=0.518, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Upper respiratory tract infection	Moderate	0%	4.1% (1.3, 12.0)	P=1.000, I <sup>2</sup> =0%	P=0.741, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.041 (-0.087 - 0.004)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.762, I <sup>2</sup> =0%	
Infections and infestations	Upper respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Nasopharyngitis		6.5% (3.4, 12.1)	11.0% (5.6, 20.4)	P=0.035, I <sup>2</sup> =66.1%	P=0.276, I <sup>2</sup> =6%							
Infections and infestations	Nasopharyngitis	Mild	5.8% (2.9, 11.2)	11.0% (5.6, 20.4)	P=0.061, I <sup>2</sup> =59.3%	P=0.276, I <sup>2</sup> =6%	0.491 (0.174, 1.384)	0.527 (0.208, 1.334) 0.176	-0.052 (-0.133 - 0.029)	P=0.554, I <sup>2</sup> =0%	P=0.527, I <sup>2</sup> =0%	P=0.910, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Nasopharyngitis	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Nasopharyngitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis		4.3% (2.0, 9.3)	11.0% (5.6, 20.4)	P=0.009, I <sup>2</sup> =0%	P=0.052, I <sup>2</sup> =62%							
Infections and infestations	Pharyngitis	Mild	4.3% (2.0, 9.3)	11.0% (5.6, 20.4)	P=0.009, I <sup>2</sup> =0%	P=0.052, I <sup>2</sup> =62%	0.351 (0.114, 1.085)	0.394 (0.145, 1.071) 0.068	-0.067 (-0.145 - 0.012)	P=0.624, I <sup>2</sup> =0%	P=0.586, I <sup>2</sup> =0%	P=0.415, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Pharyngitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection		5.1% (2.4, 10.3)	5.5% (2.1, 13.7)	P=0.409 , I <sup>2</sup> =0%	P=0.755 , I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection	Mild	3.6% (1.5, 8.4)	5.5% (2.1, 13.7)	P=0.077 , I <sup>2</sup> =59%	P=0.755 , I <sup>2</sup> =0%	0.650 (0.168, 2.512)	0.664 (0.185, 2.386) 0.531	-0.018 (-0.079 - 0.042)	P=0.345, I <sup>2</sup> =0%	P=0.340, I <sup>2</sup> =0%	P=0.528, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Respiratory tract infection	Moderate	1.4% (0.4, 5.6)	0%	P=0.138, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.034)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Bronchitis		1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.819, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Infections and infestations	Bronchitis	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Bronchitis	Moderate	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.187, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	0.531 (0.033, 8.452)	0.531 (0.034, 8.388) 0.653	-0.006 (-0.037 - 0.024)	P=0.332, I <sup>2</sup> =0%	P=0.333, I <sup>2</sup> =0%	P=0.351, I <sup>2</sup> =0%	
Infections and infestations	Bronchitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis		2.2% (0.7, 6.5)	2.7% (0.7, 10.3)	P=0.021, I <sup>2</sup> =0%	P=0.061, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis	Mild	2.2% (0.7, 6.5)	2.7% (0.7, 10.3)	P=0.021, I <sup>2</sup> =0%	P=0.061, I <sup>2</sup> =0%	0.791 (0.125, 5.004)	0.802 (0.141, 4.546) 0.803	-0.005 (-0.049 - 0.038)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Tonsillitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rhinitis		3.6% (1.5, 8.4)	1.4% (0.2, 9.1)	P=0.925, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							
Infections and infestations	Rhinitis	Mild	3.6% (1.5, 8.4)	1.4% (0.2, 9.1)	P=0.925, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	2.713 (0.310, 23.757)	2.654 (0.314, 22.415) 0.37	0.023 (-0.018 - 0.064)	P=0.435, I <sup>2</sup> =0%	P=0.431, I <sup>2</sup> =0%	P=0.545, I <sup>2</sup> =0%	
Infections and infestations	Rhinitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Rhinitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis		2.2% (0.7, 6.5)	4.1% (1.3, 12.0)	P=0.068, I <sup>2</sup> =0%	P=0.741, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis	Mild	2.2% (0.7, 6.5)	2.7% (0.7, 10.3)	P=0.068, I <sup>2</sup> =0%	P=0.828, I <sup>2</sup> =0%	0.786 (0.128, 4.813)	0.790 (0.134, 4.653) 0.794	-0.006 (-0.050 - 0.039)	P=0.272, I <sup>2</sup> =1703%	P=0.274, I <sup>2</sup> =1650%	P=0.301, I <sup>2</sup> =646%	
Infections and infestations	Gastroenteritis	Moderate	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Gastroenteritis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinusitis		0.7% (0.1, 5.0)	4.1% (1.3, 12.0)	P=0.295, I <sup>2</sup> =0%	P=0.741, I <sup>2</sup> =0%							
Infections and infestations	Sinusitis	Mild	0%	2.7% (0.7, 10.3)	P=1.000, I <sup>2</sup> =0%	P=0.133, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.065 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Sinusitis	Moderate	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	0.528 (0.033, 8.486)	0.528 (0.033, 8.551) 0.653	-0.006 (-0.037 - 0.024)	P=0.340, I <sup>2</sup> =0%	P=0.342, I <sup>2</sup> =0%	P=0.311, I <sup>2</sup> =247%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Sinusitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pneumonia		0%	4.1% (1.3, 12.0)	P=1.000, I <sup>2</sup> =0%	P=0.741, I <sup>2</sup> =0%							
Infections and infestations	Pneumonia	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pneumonia	Moderate	0%	2.7% (0.7, 10.3)	P=1.000, I <sup>2</sup> =0%	P=0.133, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.065 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Pneumonia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis streptococcal		2.2% (0.7, 6.5)	5.5% (2.1, 13.7)	P=0.068, I <sup>2</sup> =0%	P=0.032, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis streptococcal	Mild	1.4% (0.4, 5.6)	2.7% (0.7, 10.3)	P=0.138, I <sup>2</sup> =0%	P=0.133, I <sup>2</sup> =0%	0.513 (0.070, 3.777)	0.525 (0.077, 3.596) 0.512	-0.013 (-0.055, 0.029)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pharyngitis streptococcal	Moderate	0.7% (0.1, 5.0)	2.7% (0.7, 10.3)	P=0.295, I <sup>2</sup> =0%	P=0.133, I <sup>2</sup> =0%	0.253 (0.022, 2.877)	0.263 (0.025, 2.812) 0.269	-0.020 (-0.060, 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Pharyngitis streptococcal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral infection		2.9% (1.1, 7.5)	0%	P=0.035, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral infection	Mild	2.2% (0.7, 6.5)	0%	P=0.068, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.022 (-0.003 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Viral infection	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Viral infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Ear infection		2.9% (1.1, 7.5)	1.4% (0.2, 9.1)	P=0.035, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Infections and infestations	Ear infection	Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	0.519 (0.032, 8.512)	0.525 (0.034, 8.184)	-0.007 (-0.037 - 0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Ear infection	Moderate	2.2% (0.7, 6.5)	0%	P=0.068, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.022 (-0.003 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Ear infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection viral		2.2% (0.7, 6.5)	1.4% (0.2, 9.1)	P=0.068, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection viral	Mild	1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.138, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	1.051 (0.093, 11.942)	1.050 (0.098, 11.246) 0.968	0.001 (-0.032, 0.034)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Respiratory tract infection viral	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Respiratory tract infection viral	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Conjunctivitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis viral		1.4% (0.4, 5.6)	0%	P=0.138, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis viral	Mild	1.4% (0.4, 5.6)	0%	P=0.138, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.034)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Gastroenteritis viral	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Gastroenteritis viral	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis media acute		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Infections and infestations	Otitis media acute	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Otitis media acute	Moderate	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Otitis media acute	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Varicella		2.2% (0.7, 6.5)	0%	P=0.755, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Varicella	Mild	1.4% (0.4, 5.6)	0%	P=0.819, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.005 - 0.034)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.706, I <sup>2</sup> =0%	
Infections and infestations	Varicella	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Varicella	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Enteritis infectious		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Infections and infestations	Enteritis infectious	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Enteritis infectious	Moderate	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Enteritis infectious	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Enterobiasis		1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.138, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Infections and infestations	Enterobiasis	Mild	1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.138, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	1.051 (0.093, 11.942)	1.050 (0.098, 11.246) 0.968	0.001 (-0.032, 0.034)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Enterobiasis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Enterobiasis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Influenza		1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.819, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Infections and infestations	Influenza	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Influenza	Moderate	1.4% (0.4, 5.6)	0%	P=0.819, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.005 - 0.034)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.706, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Influenza	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Herpangina		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Herpangina	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Herpangina	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Herpangina	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Otitis media		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							
Infections and infestations	Otitis media	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Otitis media	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis media	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Periodontitis		1.4% (0.4, 5.6)	0%	P=0.061, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Periodontitis	Mild	1.4% (0.4, 5.6)	0%	P=0.061, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.005 - 0.035)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Periodontitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Periodontitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Urinary tract infection		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							
Infections and infestations	Urinary tract infection	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Urinary tract infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Urinary tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Helminthic infection		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Helminthic infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Helminthic infection	Moderate	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	0.519 (0.032, 8.512)	0.525 (0.034, 8.184) 0.646	-0.007 (-0.037, 0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Helminthic infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hordeolum		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.187, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Hordeolum	Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.187, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	0.531 (0.033, 8.452)	0.531 (0.034, 8.388) 0.653	-0.006 (-0.037 - 0.024)	P=0.332, I <sup>2</sup> =0%	P=0.333, I <sup>2</sup> =0%	P=0.351, I <sup>2</sup> =0%	
Infections and infestations	Hordeolum	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hordeolum	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngotonsillitis		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Pharyngoton sillitis	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pharyngoton sillitis	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pharyngoton sillitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pulpitis dental		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Pulpitis dental	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pulpitis dental	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pulpitis dental	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral upper respiratory tract infection		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Viral upper respiratory tract infection	Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	0.519 (0.032, 8.512)	0.525 (0.034, 8.184) 0.646	-0.007 (-0.037, 0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Viral upper respiratory tract infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral upper respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hand-foot-and-mouth disease		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Hand-foot-and-mouth disease	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hand-foot-and-mouth disease	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hand-foot-and-mouth disease	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Laryngitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Laryngitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Laryngitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Laryngitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Oral herpes		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							
Infections and infestations	Oral herpes	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Oral herpes	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Oral herpes	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Eczema infected		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Eczema infected	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Eczema infected	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Eczema infected	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Laryngitis viral		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Laryngitis viral	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Laryngitis viral	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Laryngitis viral	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Rotavirus infection		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Rotavirus infection	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Rotavirus infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Rotavirus infection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Vulvitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Vulvitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Vulvitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Vulvitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Appendicitis		0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Appendicitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Appendicitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Appendicitis	Severe	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Atypical pneumonia		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Atypical pneumonia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Atypical pneumonia	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Atypical pneumonia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis bacterial		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Conjunctivitis bacterial	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Conjunctivitis bacterial	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis bacterial	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Croup infectious		0%	1.7% (0.4, 6.7)	P=1.000, I <sup>2</sup> =0%	P=0.530, I <sup>2</sup> =0%							
Infections and infestations	Croup infectious	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Croup infectious	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Croup infectious	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Cystitis		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Cystitis	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Cystitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Cystitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Infected bite		0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Infected bite	Mild	0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Infected bite	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Infected bite	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Molluscum contagiosum		0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Molluscum contagiosum	Mild	0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Infections and infestations	Molluscum contagiosum	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Molluscum contagiosum	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis externa		0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis externa	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis externa	Moderate	0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Otitis externa	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tinea pedis		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tinea pedis	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Tinea pedis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Tinea pedis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tooth abscess		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tooth abscess	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Tooth abscess	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tooth abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Bacterial infection		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Bacterial infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Bacterial infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Bacterial infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Folliculitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Folliculitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Folliculitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Folliculitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Gastrointestinal bacterial infection		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Gastrointestinal bacterial infection	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Gastrointestinal bacterial infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Gastrointestinal bacterial infection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Herpes virus infection		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Herpes virus infection	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Herpes virus infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Herpes virus infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Infectious mononucleosis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Infectious mononucleosis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Infectious mononucleosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Infectious mononucleosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Mumps		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Mumps	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Mumps	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Mumps	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Peritonsillar abscess		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Peritonsillar abscess	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Peritonsillar abscess	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Peritonsillar abscess	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Sinobronchitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinobronchitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinobronchitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinobronchitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Subcutaneous abscess		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Subcutaneous abscess	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Subcutaneous abscess	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Subcutaneous abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Abscess limb		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Abscess limb	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Abscess limb	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Abscess limb	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Chronic sinusitis		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Chronic sinusitis	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Chronic sinusitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Chronic sinusitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Chronic tonsillitis		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Chronic tonsillitis	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Chronic tonsillitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Chronic tonsillitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Myringitis		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Myringitis	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Myringitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Myringitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis bacterial		0.7% (0.1, 5.0)	0%	P=0.187 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis bacterial	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Infections and infestations	Tonsillitis bacterial	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis bacterial	Severe	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Tracheitis		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tracheitis	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Infections and infestations	Tracheitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tracheitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations			23.2% (16.9, 31.0)	31.5% (21.9, 43.0)	P=0.000, I <sup>2</sup> =95.3%	P=0.000, I <sup>2</sup> =95%							
Investigations		Mild	23.2% (16.9, 31.0)	31.5% (21.9, 43.0)	P=0.000, I <sup>2</sup> =95.3%	P=0.000, I <sup>2</sup> =95%	0.569 (0.270, 1.200)	0.741 (0.504, 1.091) 0.129	-0.081 (-0.191, 0.029)	P=0.322, I <sup>2</sup> =0%	P=0.543, I <sup>2</sup> =0%	P=0.043, I <sup>2</sup> =7554%	
Investigations		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood glucose increased		9.4% (5.5, 15.5)	19.2% (11.7, 29.8)	P=0.000, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%							
Investigations	Blood glucose increased	Mild	9.4% (5.5, 15.5)	19.2% (11.7, 29.8)	P=0.000, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%	0.351 (0.137, 0.897)	0.496 (0.268, 0.919) 0.026	-0.096 (-0.189, -0.004)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood glucose increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Blood glucose increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Insulin-like growth factor increased		9.4% (5.5, 15.5)	2.7% (0.7, 10.3)	P=0.000, I <sup>2</sup> =87.8%	P=0.061, I <sup>2</sup> =0%							
Investigations	Insulin-like growth factor increased	Mild	9.4% (5.5, 15.5)	2.7% (0.7, 10.3)	P=0.000, I <sup>2</sup> =87.8%	P=0.061, I <sup>2</sup> =0%	4.116 (0.865, 19.579)	3.471 (0.832, 14.488) 0.088	0.067 (0.008 - 0.127)	P=0.560, I <sup>2</sup> =0%	P=0.622, I <sup>2</sup> =0%	P=0.003, I <sup>2</sup> =8842%	
Investigations	Insulin-like growth factor increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Insulin-like growth factor increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Low density lipoprotein increased		0.7% (0.1, 5.0)	4.1% (1.3, 12.0)	P=0.187, I <sup>2</sup> =0%	P=0.021, I <sup>2</sup> =0%							
Investigations	Low density lipoprotein increased	Mild	0.7% (0.1, 5.0)	4.1% (1.3, 12.0)	P=0.187, I <sup>2</sup> =0%	P=0.021, I <sup>2</sup> =0%	0.164 (0.016, 1.646)	0.178 (0.019, 1.642) 0.128	-0.034 (-0.081, 0.014)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Investigation s	Low density lipoprotein increased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Low density lipoprotein increased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood alkaline phosphatase increased		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.187 , I <sup>2</sup> =0%	P=0.188 , I <sup>2</sup> =0%							
Investigation s	Blood alkaline phosphatase increased	Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.187 , I <sup>2</sup> =0%	P=0.188 , I <sup>2</sup> =0%	0.526 (0.032, 8.714)	0.534 (0.035, 8.255)	-0.006 (-0.036 - 0.024)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Blood alkaline phosphatase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood alkaline phosphatase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Eosinophil count increased		1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.819, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Eosinophil count increased	Mild	1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.819, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	1.064 (0.094, 12.003)	1.063 (0.098, 11.544) 0.96	0.001 (-0.032, 0.034)	P=0.581, I <sup>2</sup> =0%	P=0.581, I <sup>2</sup> =0%	P=0.605, I <sup>2</sup> =0%	
Investigations	Eosinophil count increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Eosinophil count increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Alanine aminotransferase increased		2.2% (0.7, 6.5)	1.4% (0.2, 9.1)	P=0.021, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Investigations	Alanine aminotransferase increased	Mild	2.2% (0.7, 6.5)	1.4% (0.2, 9.1)	P=0.021, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	1.594 (0.167, 15.160)	1.594 (0.167, 15.189) 0.685	0.008 (-0.028, 0.045)	P=0.139, I <sup>2</sup> =5439%	P=0.140, I <sup>2</sup> =5398%	P=0.116, I <sup>2</sup> =5949%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Alanine aminotransferase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Alanine aminotransferase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron increased		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.187, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Investigations	Blood iron increased	Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.187, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	0.531 (0.033, 8.452)	0.531 (0.034, 8.388) 0.653	-0.006 (-0.037, 0.024)	P=0.332, I <sup>2</sup> =0%	P=0.333, I <sup>2</sup> =0%	P=0.351, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Blood iron increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood phosphorus increased		2.2% (0.7, 6.5)	0%	P=0.021, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood phosphorus increased	Mild	2.2% (0.7, 6.5)	0%	P=0.021, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.022 (-0.003 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Investigation s	Blood phosphorus increased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood phosphorus increased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood uric acid increased		1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.061 , I <sup>2</sup> =0%	P=0.188 , I <sup>2</sup> =0%							
Investigation s	Blood uric acid increased	Mild	1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.061 , I <sup>2</sup> =0%	P=0.188 , I <sup>2</sup> =0%	1.071 (0.093, 12.306)	1.069 (0.101, 11.327)	0.001 (-0.032 - 0.034)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Investigation s	Blood uric acid increased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Blood uric acid increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol decreased		1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.061, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							
Investigations	Cortisol decreased	Mild	1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.061, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	1.071 (0.093, 12.306)	1.069 (0.101, 11.327) 0.956	0.001 (-0.032, 0.034)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Cortisol decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Investigation s	Cortisol decreased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Aspartate aminotransfe rase increased		1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.061 , I <sup>2</sup> =0%	P=0.291 , I <sup>2</sup> =0%							
Investigation s	Aspartate aminotransfe rase increased	Mild	1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.061 , I <sup>2</sup> =0%	P=0.291 , I <sup>2</sup> =0%	1.062 (0.097, 11.654)	1.062 (0.097, 11.604) 0.96	0.001 (-0.033 - 0.034)	P=0.20 5, I <sup>2</sup> =377 9%	P=0.20 7, I <sup>2</sup> =372 8%	P=0.20 7, I <sup>2</sup> =371 8%	
Investigation s	Aspartate aminotransfe rase increased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Aspartate aminotransferase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood triglycerides increased		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood triglycerides increased	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood triglycerides increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood triglycerides increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Blood glucose abnormal		0%	2.7% (0.7, 10.3)	P=1.000, I <sup>2</sup> =0%	P=0.061, I <sup>2</sup> =0%							
Investigations	Blood glucose abnormal	Mild	0%	2.7% (0.7, 10.3)	P=1.000, I <sup>2</sup> =0%	P=0.061, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.065 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood glucose abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood glucose abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Blood thyroid stimulating hormone increased		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood thyroid stimulating hormone increased	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood thyroid stimulating hormone increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Blood thyroid stimulating hormone increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	White blood cell count decreased		1.4% (0.4, 5.6)	0%	P=0.819, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	White blood cell count decreased	Mild	1.4% (0.4, 5.6)	0%	P=0.819, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.005 - 0.034)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.706, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	White blood cell count decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	White blood cell count decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Tri-iodothyronine free increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Tri-iodothyronine free increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Investigation s	Tri-iodothyronine free increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigation s	Tri-iodothyronine free increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigation s	Electrocardiogram T wave peaked		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigation s	Electrocardiogram T wave peaked	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Electrocardiogram T wave peaked	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram T wave peaked	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood urea increased		0%	2.7% (0.7, 10.3)	P=1.000, I <sup>2</sup> =0%	P=0.061, I <sup>2</sup> =0%							
Investigations	Blood urea increased	Mild	0%	2.7% (0.7, 10.3)	P=1.000, I <sup>2</sup> =0%	P=0.061, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.027 (-0.065 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood urea increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Investigation s	Blood urea increased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood cortisol decreased		0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood cortisol decreased	Mild	0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Investigation s	Blood cortisol decreased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Blood cortisol decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron decreased		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Investigations	Blood iron decreased	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood iron decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Investigation s	Blood iron decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigation s	Cortisol free urine decreased		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigation s	Cortisol free urine decreased	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigation s	Cortisol free urine decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigation s	Cortisol free urine decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Thyroxine decreased		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Investigations	Thyroxine decreased	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Thyroxine decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Transaminases increased		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Transaminases increased	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Transaminases increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Transaminases increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Basophil count increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Basophil count increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Basophil count increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Basophil count increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Blood cholesterol increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood lactate dehydrogenase increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Blood lactate dehydrogenase increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood lactate dehydrogenase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood lactate dehydrogenase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood potassium increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Blood potassium increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood potassium increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood potassium increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood pressure increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood pressure increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Blood pressure increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood pressure increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram ST segment abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram ST segment abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Electrocardiogram ST segment abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram ST segment abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Haemoglobin decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Haemoglobin decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Haemoglobin decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Investigation s	Haemoglobi n decreased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Electrocardi ogram high voltage		0.7% (0.1, 5.0)	0%	P=0.187 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Electrocardi ogram high voltage	Mild	0.7% (0.1, 5.0)	0%	P=0.187 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
Investigation s	Electrocardi ogram high voltage	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Electrocardiogram high voltage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme abnormal		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme abnormal	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Hepatic enzyme abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Hepatic enzyme increased		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme increased	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Hepatic enzyme increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Lipids increased		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							
Investigations	Lipids increased	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Lipids increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Lipids increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Liver function test abnormal		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							
Investigations	Liver function test abnormal	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Liver function test abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Liver function test abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Thyroid function test abnormal		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							
Investigations	Thyroid function test abnormal	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Thyroid function test abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Thyroid function test abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine free decreased		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine free decreased	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Thyroxine free decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Investigations	Thyroxine free decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders			24.6% (18.2, 32.5)	20.5% (12.8, 31.3)	P=0.777, I <sup>2</sup> =0%	P=0.342, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders		Mild	21.0% (15.0, 28.6)	16.4% (9.6, 26.8)	P=0.236, I <sup>2</sup> =28.7%	P=0.226, I <sup>2</sup> =30%	1.362 (0.645, 2.877)	1.281 (0.699, 2.348) 0.423	0.046 (-0.062, 0.154)	P=0.723, I <sup>2</sup> =0%	P=0.690, I <sup>2</sup> =0%	P=0.837, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders		Moderate	3.6% (1.5, 8.4)	4.1% (1.3, 12.0)	P=0.018, I <sup>2</sup> =0%	P=0.741, I <sup>2</sup> =0%	0.871 (0.201, 3.778)	0.877 (0.216, 3.557) 0.854	-0.005 (-0.060 - 0.050)	P=0.273, I <sup>2</sup> =1680%	P=0.274, I <sup>2</sup> =1648%	P=0.332, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Cough		13.0% (8.4, 19.8)	12.3% (6.5, 22.0)	P=0.024, I <sup>2</sup> =79.1%	P=0.399, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Cough	Mild	13.0% (8.4, 19.8)	9.6% (4.6, 18.8)	P=0.024, I <sup>2</sup> =79.1%	P=0.412, I <sup>2</sup> =0%	1.430 (0.564, 3.627)	1.365 (0.603, 3.094) 0.456	0.035 (-0.052, 0.122)	P=0.595, I <sup>2</sup> =0%	P=0.624, I <sup>2</sup> =0%	P=0.407, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Cough	Moderate	0%	2.7% (0.7, 10.3)	P=1.000, I <sup>2</sup> =0%	P=0.828, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.065, 0.010)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.776, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Cough	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea		0.7% (0.1, 5.0)	6.8% (2.9, 15.4)	P=0.187, I <sup>2</sup> =0%	P=0.414, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Mild	0.7% (0.1, 5.0)	6.8% (2.9, 15.4)	P=0.187, I <sup>2</sup> =0%	P=0.414, I <sup>2</sup> =0%	0.097 (0.011, 0.867)	0.107 (0.013, 0.885) 0.038	-0.061 (-0.121, -0.002)	P=0.658, I <sup>2</sup> =0%	P=0.651, I <sup>2</sup> =0%	P=0.679, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic		2.2% (0.7, 6.5)	1.4% (0.2, 9.1)	P=0.755, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Mild	2.2% (0.7, 6.5)	1.4% (0.2, 9.1)	P=0.755, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	1.601 (0.164, 15.676)	1.591 (0.167, 15.167) 0.686	0.008 (-0.028 - 0.044)	P=0.397, I <sup>2</sup> =0%	P=0.396, I <sup>2</sup> =0%	P=0.436, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Asthma		1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.819, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Asthma	Mild	1.4% (0.4, 5.6)	0%	P=0.819, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.015 (-0.005 - 0.034)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.706, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Asthma	Moderate	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Asthma	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Respiratory disorder		1.4% (0.4, 5.6)	2.7% (0.7, 10.3)	P=0.138, I <sup>2</sup> =0%	P=0.133, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	0.519 (0.032, 8.512)	0.525 (0.034, 8.184) 0.646	-0.007 (-0.037, 0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Moderate	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	0.519 (0.032, 8.512)	0.525 (0.034, 8.184) 0.646	-0.007 (-0.037 - 0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Epistaxis		1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.138, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Epistaxis	Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	0.519 (0.032, 8.512)	0.525 (0.034, 8.184) 0.646	-0.007 (-0.037 - 0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Epistaxis	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Epistaxis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal congestion		1.4% (0.4, 5.6)	2.7% (0.7, 10.3)	P=0.138, I <sup>2</sup> =0%	P=0.828, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Mild	0.7% (0.1, 5.0)	2.7% (0.7, 10.3)	P=0.295, I <sup>2</sup> =0%	P=0.828, I <sup>2</sup> =0%	0.259 (0.023, 2.910)	0.263 (0.024, 2.879) 0.274	-0.020 (-0.060, 0.020)	P=0.586, I <sup>2</sup> =0%	P=0.586, I <sup>2</sup> =0%	P=0.567, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sinus congestion		1.4% (0.4, 5.6)	0%	P=0.138, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Wheezing		1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.138, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Wheezing	Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	0.519 (0.032, 8.512)	0.525 (0.034, 8.184) 0.646	-0.007 (-0.037, 0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Wheezing	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007, 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Wheezing	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Allergic cough		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Allergic cough	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Allergic cough	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Allergic cough	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Laryngospasm		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Nasal obstruction		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Productive cough		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Productive cough	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Productive cough	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Productive cough	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders			21.7% (15.6, 29.4)	19.2% (11.7, 29.8)	P=0.799, I <sup>2</sup> =0%	P=0.974, I <sup>2</sup> =0%							
Gastrointestinal disorders		Mild	21.0% (15.0, 28.6)	16.4% (9.6, 26.8)	P=0.936, I <sup>2</sup> =0%	P=0.565, I <sup>2</sup> =0%	1.353 (0.644, 2.842)	1.279 (0.695, 2.355) 0.43	0.046 (-0.063, 0.155)	P=0.601, I <sup>2</sup> =0%	P=0.596, I <sup>2</sup> =0%	P=0.619, I <sup>2</sup> =0%	
Gastrointestinal disorders		Moderate	0.7% (0.1, 5.0)	2.7% (0.7, 10.3)	P=0.295, I <sup>2</sup> =0%	P=0.133, I <sup>2</sup> =0%	0.253 (0.022, 2.877)	0.263 (0.025, 2.812) 0.269	-0.020 (-0.060, -0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Gastrointestinal disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Diarrhoea		5.8% (2.9, 11.2)	8.2% (3.7, 17.1)	P=0.788, I <sup>2</sup> =0%	P=0.698, I <sup>2</sup> =0%							
Gastrointestinal disorders	Diarrhoea	Mild	5.8% (2.9, 11.2)	8.2% (3.7, 17.1)	P=0.788, I <sup>2</sup> =0%	P=0.698, I <sup>2</sup> =0%	0.687 (0.229, 2.062)	0.705 (0.254, 1.958) 0.503	-0.024 (-0.098, 0.050)	P=0.640, I <sup>2</sup> =0%	P=0.640, I <sup>2</sup> =0%	P=0.639, I <sup>2</sup> =0%	
Gastrointestinal disorders	Diarrhoea	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Gastrointestinal disorders	Diarrhoea	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Vomiting		5.8% (2.9, 11.2)	4.1% (1.3, 12.0)	P=0.061, I <sup>2</sup> =59.3%	P=0.065, I <sup>2</sup> =0%							
Gastrointestinal disorders	Vomiting	Mild	5.8% (2.9, 11.2)	2.7% (0.7, 10.3)	P=0.061, I <sup>2</sup> =59.3%	P=0.133, I <sup>2</sup> =0%	2.209 (0.449, 10.859)	2.103 (0.465, 9.510) 0.334	0.030 (-0.023 - 0.084)	P=0.804, I <sup>2</sup> =0%	P=0.814, I <sup>2</sup> =0%	P=0.475, I <sup>2</sup> =0%	
Gastrointestinal disorders	Vomiting	Moderate	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Gastrointestinal disorders	Vomiting	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Nausea		3.6% (1.5, 8.4)	2.7% (0.7, 10.3)	P=0.288, I <sup>2</sup> =0%	P=0.133, I <sup>2</sup> =0%							
Gastrointestinal disorders	Nausea	Mild	2.9% (1.1, 7.5)	1.4% (0.2, 9.1)	P=0.471, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	2.149 (0.234, 19.721)	2.106 (0.242, 18.361) 0.5	0.015 (-0.023 - 0.054)	P=0.763, I <sup>2</sup> =0%	P=0.763, I <sup>2</sup> =0%	P=0.853, I <sup>2</sup> =0%	
Gastrointestinal disorders	Nausea	Moderate	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	0.519 (0.032, 8.512)	0.525 (0.034, 8.184) 0.646	-0.007 (-0.037 - 0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Gastrointestinal disorders	Nausea	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Dyspepsia		1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.061, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							
Gastrointestinal disorders	Dyspepsia	Mild	1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.061, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	1.071 (0.093, 12.306)	1.069 (0.101, 11.327) 0.956	0.001 (-0.032, 0.034)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Dyspepsia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Gastrointestinal disorders	Dyspepsia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal pain		2.9% (1.1, 7.5)	1.4% (0.2, 9.1)	P=0.471, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal pain	Mild	2.2% (0.7, 6.5)	1.4% (0.2, 9.1)	P=0.755, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	1.596 (0.163, 15.661)	1.581 (0.168, 14.848) 0.688	0.008 (-0.028 - 0.044)	P=0.736, I <sup>2</sup> =0%	P=0.735, I <sup>2</sup> =0%	P=0.811, I <sup>2</sup> =0%	
Gastrointestinal disorders	Abdominal pain	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Gastrointesti nal disorders	Abdominal pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Abdominal pain upper		3.6% (1.5, 8.4)	1.4% (0.2, 9.1)	P=0.925 , I <sup>2</sup> =0%	P=0.291 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Abdominal pain upper	Mild	3.6% (1.5, 8.4)	1.4% (0.2, 9.1)	P=0.925 , I <sup>2</sup> =0%	P=0.291 , I <sup>2</sup> =0%	2.701 (0.309, 23.588)	2.637 (0.315, 22.070) 0.371	0.022 (-0.019 - 0.064)	P=0.65 3, I <sup>2</sup> =0%	P=0.65 1, I <sup>2</sup> =0%	P=0.76 1, I <sup>2</sup> =0%	
Gastrointesti nal disorders	Abdominal pain upper	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Abdominal pain upper	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Gastrointesti nal disorders	Constipation		1.4% (0.4, 5.6)	0%	P=0.138 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Constipation	Mild	0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
Gastrointesti nal disorders	Constipation	Moderate	0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
Gastrointesti nal disorders	Constipation	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Gastrointestinal disorders	Toothache		1.4% (0.4, 5.6)	2.7% (0.7, 10.3)	P=0.819, I <sup>2</sup> =0%	P=0.828, I <sup>2</sup> =0%							
Gastrointestinal disorders	Toothache	Mild	1.4% (0.4, 5.6)	2.7% (0.7, 10.3)	P=0.819, I <sup>2</sup> =0%	P=0.828, I <sup>2</sup> =0%	0.523 (0.072, 3.791)	0.530 (0.076, 3.682) 0.521	-0.013 (-0.055, 0.030)	P=0.994, I <sup>2</sup> =0%	P=0.993, I <sup>2</sup> =0%	P=0.933, I <sup>2</sup> =0%	
Gastrointestinal disorders	Toothache	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Toothache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Gastrointestinal disorders	Abdominal discomfort		1.4% (0.4, 5.6)	0%	P=0.138, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal discomfort	Mild	1.4% (0.4, 5.6)	0%	P=0.138, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.034)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Abdominal discomfort	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Gastrointesti nal disorders	Enteritis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Enteritis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Enteritis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Enteritis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastrointesti nal disorder		0.7% (0.1, 5.0)	0%	P=0.187 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Gastrointestinal disorders	Gastrointestinal disorder	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Gastrointestinal disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastrointestinal disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastrointestinal motility disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Gastrointestinal disorders	Gastrointestinal motility disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastrointestinal motility disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastrointestinal motility disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Lip swelling		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Lip swelling	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Gastrointesti nal disorders	Lip swelling	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Lip swelling	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Aphthous ulcer		0%	1.4% (0.2, 9.1)	P=1.000 , I <sup>2</sup> =0%	P=0.291 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Aphthous ulcer	Mild	0%	1.4% (0.2, 9.1)	P=1.000 , I <sup>2</sup> =0%	P=0.291 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Gastrointestinal disorders	Aphthous ulcer	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Aphthous ulcer	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastric disorder		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastric disorder	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Gastric disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Gastrointestinal disorders	Gastric disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal distension		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal distension	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Abdominal distension	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Gastrointestinal disorders	Abdominal distension	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Noninfective gingivitis		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							
Gastrointestinal disorders	Noninfective gingivitis	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Noninfective gingivitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Gastrointestinal disorders	Noninfective gingivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions			18.8% (13.2, 26.2)	23.3% (15.0, 34.3)	P=0.975, I <sup>2</sup> =0%	P=0.321, I <sup>2</sup> =0%							
General disorders and administration site conditions		Mild	15.2% (10.1, 22.2)	20.5% (12.8, 31.3)	P=0.575, I <sup>2</sup> =0%	P=0.125, I <sup>2</sup> =56%	0.693 (0.332, 1.448)	0.742 (0.409, 1.347) 0.327	-0.053 (-0.163, 0.057)	P=0.407, I <sup>2</sup> =0%	P=0.434, I <sup>2</sup> =0%	P=0.323, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions		Moderate	3.6% (1.5, 8.4)	2.7% (0.7, 10.3)	P=0.288, I <sup>2</sup> =0%	P=0.133, I <sup>2</sup> =0%	1.332 (0.249, 7.113)	1.316 (0.264, 6.544) 0.738	0.009 (-0.040 - 0.057)	P=0.769, I <sup>2</sup> =0%	P=0.766, I <sup>2</sup> =0%	P=0.874, I <sup>2</sup> =0%	
General disorders and administration site conditions		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Pyrexia		16.7% (11.3, 23.8)	12.3% (6.5, 22.0)	P=0.757, I <sup>2</sup> =0%	P=0.399, I <sup>2</sup> =0%							
General disorders and administration site conditions	Pyrexia	Mild	13.8% (9.0, 20.6)	12.3% (6.5, 22.0)	P=0.613, I <sup>2</sup> =0%	P=0.399, I <sup>2</sup> =0%	1.138 (0.486, 2.666)	1.118 (0.534, 2.342) 0.767	0.015 (-0.080 - 0.109)	P=0.687, I <sup>2</sup> =0%	P=0.682, I <sup>2</sup> =0%	P=0.716, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Pyrexia	Moderate	2.9% (1.1, 7.5)	0%	P=0.035, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.029 (0.001 - 0.057)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Pyrexia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site pain		1.4% (0.4, 5.6)	0%	P=0.061, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Injection site pain	Mild	1.4% (0.4, 5.6)	0%	P=0.061, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.005 - 0.035)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Injection site pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Injection site pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site pruritus		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.187, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Injection site pruritus	Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.187, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	0.526 (0.032, 8.714)	0.534 (0.035, 8.255) 0.654	-0.006 (-0.036 - 0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Injection site pruritus	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site pruritus	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Fatigue		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
General disorders and administration site conditions	Fatigue	Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	0.519 (0.032, 8.512)	0.525 (0.034, 8.184) 0.646	-0.007 (-0.037 - 0.024)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
General disorders and administrati on site conditions	Fatigue	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Fatigue	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
General disorders and administrati on site conditions	Injection site swelling		0%	2.7% (0.7, 10.3)	P=1.000 , I <sup>2</sup> =0%	P=0.828 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site swelling	Mild	0%	2.7% (0.7, 10.3)	P=1.000 , I <sup>2</sup> =0%	P=0.828 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.065 - 0.010)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.776, I <sup>2</sup> =0%	
General disorders and administrati on site conditions	Injection site swelling	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Injection site swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site erythema		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Injection site erythema	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Injection site erythema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Injection site erythema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site reaction		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site reaction	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Injection site reaction	Moderate	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Injection site reaction	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Gait disturbance		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Gait disturbance	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Gait disturbance	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Gait disturbance	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Face oedema		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Face oedema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Face oedema	Moderate	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Face oedema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Influenza like illness		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Influenza like illness	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Influenza like illness	Moderate	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Influenza like illness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
General disorders and administrati on site conditions	Injection site atrophy		0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site atrophy	Mild	0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
General disorders and administrati on site conditions	Injection site atrophy	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site atrophy	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
General disorders and administrati on site conditions	Injection site urticaria		0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site urticaria	Mild	0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
General disorders and administrati on site conditions	Injection site urticaria	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Injection site urticaria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Medical device discomfort		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Medical device discomfort	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Medical device discomfort	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Medical device discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Vaccination site pain		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
General disorders and administration site conditions	Vaccination site pain	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
General disorders and administrati on site conditions	Vaccination site pain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Vaccination site pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Injection site haemorrhage		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site haemorrhage	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Injection site haemorrhage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site haemorrhage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site bruising		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Injection site bruising	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Injection site bruising	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Injection site bruising	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Pain		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Pain	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
General disorders and administrati on site conditions	Peripheral swelling		0.7% (0.1, 5.0)	0%	P=0.187 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Peripheral swelling	Mild	0.7% (0.1, 5.0)	0%	P=0.187 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
General disorders and administration site conditions	Peripheral swelling	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Peripheral swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders			10.9% (6.7, 17.2)	19.2% (11.7, 29.8)	P=0.011, I <sup>2</sup> =78.7%	P=0.567, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Nervous system disorders		Mild	8.0% (4.5, 13.8)	15.1% (8.5, 25.2)	P=0.080, I <sup>2</sup> =59.9%	P=0.828, I <sup>2</sup> =0%	0.488 (0.200, 1.188)	0.528 (0.240, 1.161) 0.112	-0.071 (-0.165, 0.023)	P=0.174, I <sup>2</sup> =459%	P=0.166, I <sup>2</sup> =478%	P=0.311, I <sup>2</sup> =263%	
Nervous system disorders		Moderate	2.9% (1.1, 7.5)	4.1% (1.3, 12.0)	P=0.035, I <sup>2</sup> =0%	P=0.065, I <sup>2</sup> =0%	0.684 (0.146, 3.211)	0.700 (0.164, 2.983) 0.63	-0.012 (-0.065, 0.040)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Nervous system disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Headache		8.7% (5.0, 14.7)	15.1% (8.5, 25.2)	P=0.000, I <sup>2</sup> =0%	P=0.655, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Nervous system disorders	Headache	Mild	5.8% (2.9, 11.2)	11.0% (5.6, 20.4)	P=0.003, I <sup>2</sup> =0%	P=0.649, I <sup>2</sup> =0%	0.502 (0.180, 1.396)	0.527 (0.205, 1.356) 0.184	-0.052 (-0.134, 0.030)	P=0.058, I <sup>2</sup> =720 8%	P=0.059, I <sup>2</sup> =719 7%	P=0.103, I <sup>2</sup> =623 2%	
Nervous system disorders	Headache	Moderate	2.9% (1.1, 7.5)	4.1% (1.3, 12.0)	P=0.035, I <sup>2</sup> =0%	P=0.065, I <sup>2</sup> =0%	0.684 (0.146, 3.211)	0.700 (0.164, 2.983) 0.63	-0.012 (-0.065, 0.040)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Nervous system disorders	Headache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Dizziness		2.9% (1.1, 7.5)	2.7% (0.7, 10.3)	P=0.745, I <sup>2</sup> =0%	P=0.828, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Nervous system disorders	Dizziness	Mild	2.9% (1.1, 7.5)	2.7% (0.7, 10.3)	P=0.745, I <sup>2</sup> =0%	P=0.828, I <sup>2</sup> =0%	1.061 (0.190, 5.940)	1.059 (0.199, 5.644) 0.946	0.002 (-0.045, 0.048)	P=0.991, I <sup>2</sup> =0%	P=0.992, I <sup>2</sup> =0%	P=0.983, I <sup>2</sup> =0%	
Nervous system disorders	Dizziness	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Dizziness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Post-traumatic headache		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Nervous system disorders	Post-traumatic headache	Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	0.519 (0.032, 8.512)	0.525 (0.034, 8.184) 0.646	-0.007 (-0.037 - 0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Nervous system disorders	Post-traumatic headache	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Post-traumatic headache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Migraine		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Nervous system disorders	Migraine	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Nervous system disorders	Migraine	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Nervous system disorders	Migraine	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Nervous system disorders	Tremor		0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Nervous system disorders	Tremor	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Nervous system disorders	Tremor	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Nervous system disorders	Tremor	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications			11.6% (7.2, 18.1)	8.2% (3.7, 17.1)	P=0.132, I <sup>2</sup> =51.4%	P=0.008, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Injury, poisoning and procedural complications		Mild	8.7% (5.0, 14.7)	6.8% (2.9, 15.4)	P=0.518, I <sup>2</sup> =0%	P=0.016, I <sup>2</sup> =0%	1.294 (0.435, 3.856)	1.265 (0.467, 3.426) 0.644	0.018 (-0.056 - 0.092)	P=0.234, I <sup>2</sup> =2929%	P=0.234, I <sup>2</sup> =2954%	P=0.227, I <sup>2</sup> =3146%	
Injury, poisoning and procedural complications		Moderate	2.9% (1.1, 7.5)	1.4% (0.2, 9.1)	P=0.035, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	2.158 (0.233, 19.948)	2.100 (0.242, 18.196) 0.501	0.015 (-0.023 - 0.053)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Injury, poisoning and procedural complications	Head injury		1.4% (0.4, 5.6)	0%	P=0.819, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Head injury	Mild	1.4% (0.4, 5.6)	0%	P=0.819, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.005 - 0.034)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.706, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Head injury	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Injury, poisoning and procedural complications	Head injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Contusion		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Contusion	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Injury, poisoning and procedural complications	Contusion	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Contusion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal bite		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Injury, poisoning and procedural complications	Animal bite	Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	0.519 (0.032, 8.512)	0.525 (0.034, 8.184) 0.646	-0.007 (-0.037 - 0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Animal bite	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Injury, poisoning and procedural complications	Animal bite	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Arthropod bite		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295 , I <sup>2</sup> =0%	P=0.291 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Arthropod bite	Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295 , I <sup>2</sup> =0%	P=0.291 , I <sup>2</sup> =0%	0.519 (0.032, 8.512)	0.525 (0.034, 8.184) 0.646	-0.007 (-0.037 - 0.024)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Injury, poisoning and procedural complications	Arthropod bite	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Arthropod bite	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ligament sprain		1.4% (0.4, 5.6)	0%	P=0.819, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Injury, poisoning and procedural complications	Ligament sprain	Mild	1.4% (0.4, 5.6)	0%	P=0.819, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.005 - 0.034)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.706, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Ligament sprain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ligament sprain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Injury, poisoning and procedural complications	Post-traumatic pain		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Post-traumatic pain	Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	0.519 (0.032, 8.512)	0.525 (0.034, 8.184) 0.646	-0.007 (-0.037 - 0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Post-traumatic pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Injury, poisoning and procedural complications	Post-traumatic pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Skin laceration		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Injury, poisoning and procedural complications	Skin laceration	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Skin laceration	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Skin laceration	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Injury, poisoning and procedural complications	Burns second degree		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns second degree	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns second degree	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Injury, poisoning and procedural complications	Burns second degree	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Fall		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Fall	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Injury, poisoning and procedural complications	Fall	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Fall	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ankle fracture		0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Injury, poisoning and procedural complications	Ankle fracture	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ankle fracture	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Injury, poisoning and procedural complications	Ankle fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns first degree		0%	1.4% (0.2, 9.1)	P=1.000 , I <sup>2</sup> =0%	P=0.291 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns first degree	Mild	0%	1.4% (0.2, 9.1)	P=1.000 , I <sup>2</sup> =0%	P=0.291 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Injury, poisoning and procedural complications	Burns first degree	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns first degree	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Concussion		0%	1.4% (0.2, 9.1)	P=1.000 , I <sup>2</sup> =0%	P=0.291 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Injury, poisoning and procedural complications	Concussion	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Concussion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Concussion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Injury, poisoning and procedural complications	Face injury		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Face injury	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Face injury	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Injury, poisoning and procedural complications	Face injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Laceration		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Injury, poisoning and procedural complications	Laceration	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Laceration	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Laceration	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Injury, poisoning and procedural complications	Meniscus injury		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Meniscus injury	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Meniscus injury	Moderate	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Injury, poisoning and procedural complications	Meniscus injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Muscle strain		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Muscle strain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Injury, poisoning and procedural complications	Muscle strain	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Muscle strain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Radius fracture		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Injury, poisoning and procedural complications	Radius fracture	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Radius fracture	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Injury, poisoning and procedural complications	Radius fracture	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Thermal burn		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Thermal burn	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Injury, poisoning and procedural complications	Thermal burn	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Thermal burn	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Upper limb fracture		0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Injury, poisoning and procedural complications	Upper limb fracture	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Upper limb fracture	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Upper limb fracture	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Injury, poisoning and procedural complications	Wrist fracture		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Wrist fracture	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Wrist fracture	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Injury, poisoning and procedural complications	Wrist fracture	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal scratch		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Injury, poisoning and procedural complications	Animal scratch	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal scratch	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal scratch	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Injury, poisoning and procedural complications	Eye injury		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Eye injury	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Eye injury	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Injury, poisoning and procedural complications	Eye injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Joint injury		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Joint injury	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Injury, poisoning and procedural complications	Joint injury	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Joint injury	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders			8.0% (4.5, 13.8)	6.8% (2.9, 15.4)	P=0.811 , I <sup>2</sup> =0%	P=0.908 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Skin and subcutaneous tissue disorders		Mild	7.2% (3.9, 12.9)	4.1% (1.3, 12.0)	P=0.598, I <sup>2</sup> =0%	P=0.389, I <sup>2</sup> =0%	1.833 (0.486, 6.907)	1.768 (0.503, 6.212) 0.374	0.031 (-0.031, 0.094)	P=0.622, I <sup>2</sup> =0%	P=0.614, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders		Moderate	0.7% (0.1, 5.0)	2.7% (0.7, 10.3)	P=0.295, I <sup>2</sup> =0%	P=0.133, I <sup>2</sup> =0%	0.253 (0.022, 2.877)	0.263 (0.025, 2.812) 0.269	-0.020 (-0.060, 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Skin and subcutaneous tissue disorders	Rash		1.4% (0.4, 5.6)	2.7% (0.7, 10.3)	P=0.138, I <sup>2</sup> =0%	P=0.828, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash	Mild	1.4% (0.4, 5.6)	2.7% (0.7, 10.3)	P=0.138, I <sup>2</sup> =0%	P=0.828, I <sup>2</sup> =0%	0.521 (0.072, 3.780)	0.527 (0.075, 3.688)	-0.013 (-0.055, 0.029)	P=0.382, I <sup>2</sup> =0%	P=0.383, I <sup>2</sup> =0%	P=0.419, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Rash	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Skin and subcutaneous tissue disorders	Urticaria		1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.819, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria	Mild	1.4% (0.4, 5.6)	0%	P=0.819, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.015 (-0.005 - 0.034)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.706, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Urticaria	Moderate	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Skin and subcutaneous tissue disorders	Urticaria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis allergic		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.187, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis allergic	Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.187, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	0.526 (0.032, 8.714)	0.534 (0.035, 8.255)	-0.006 (-0.036 - 0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Dermatitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Skin and subcutaneous tissue disorders	Dermatitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Eczema		1.4% (0.4, 5.6)	0%	P=0.819, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Eczema	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Skin and subcutaneous tissue disorders	Eczema	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Eczema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis contact		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis contact	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Skin and subcutaneous tissue disorders	Dermatitis contact	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis contact	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria papular		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Skin and subcutaneous tissue disorders	Urticaria papular	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Urticaria papular	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria papular	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Cafe au lait spots		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Skin and subcutaneous tissue disorders	Cafe au lait spots	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Cafe au lait spots	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Cafe au lait spots	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Skin and subcutaneous tissue disorders	Keratosis pilaris		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Keratosis pilaris	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Keratosis pilaris	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Keratosis pilaris	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Skin and subcutaneous tissue disorders	Pityriasis alba		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Pityriasis alba	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Pityriasis alba	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Skin and subcutaneous tissue disorders	Pityriasis alba	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Petechiae		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Petechiae	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Petechiae	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Skin and subcutaneous tissue disorders	Petechiae	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash erythematous		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash erythematous	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Skin and subcutaneous tissue disorders	Rash erythematous	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash erythematous	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash pruritic		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash pruritic	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Skin and subcutaneous tissue disorders	Rash pruritic	Moderate	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Rash pruritic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Skin and subcutaneous tissue disorders	Dermatitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria chronic		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Skin and subcutaneous tissue disorders	Urticaria chronic	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria chronic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria chronic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Skin and subcutaneous tissue disorders	Dyshidrotic eczema		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Eye disorders			9.4% (5.5, 15.5)	5.5% (2.1, 13.7)	P=0.137, I <sup>2</sup> =53.2%	P=0.755, I <sup>2</sup> =0%							
Eye disorders		Mild	8.7% (5.0, 14.7)	5.5% (2.1, 13.7)	P=0.235, I <sup>2</sup> =27.9%	P=0.755, I <sup>2</sup> =0%	1.650 (0.512, 5.319)	1.591 (0.533, 4.747) 0.405	0.032 (-0.038 - 0.102)	P=0.738, I <sup>2</sup> =0%	P=0.752, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	
Eye disorders		Moderate	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Eye disorders	Refraction disorder		2.2% (0.7, 6.5)	1.4% (0.2, 9.1)	P=0.021, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							
Eye disorders	Refraction disorder	Mild	2.2% (0.7, 6.5)	1.4% (0.2, 9.1)	P=0.021, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	1.636 (0.163, 16.427)	1.603 (0.174, 14.775) 0.677	0.008 (-0.027, 0.044)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Refraction disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Refraction disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Eye disorders	Eye swelling		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye swelling	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye swelling	Moderate	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Eye swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Conjunctivitis allergic		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Eye disorders	Conjunctivitis allergic	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Conjunctivitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Conjunctivitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Myopia		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Eye disorders	Myopia	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Myopia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Myopia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Strabismus		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Eye disorders	Strabismus	Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	0.519 (0.032, 8.512)	0.525 (0.034, 8.184) 0.646	-0.007 (-0.037 - 0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Strabismus	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Strabismus	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Papilloedema		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.187, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Eye disorders	Papilloedema	Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.187, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	0.526 (0.032, 8.714)	0.534 (0.035, 8.255) 0.654	-0.006 (-0.036 - 0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Papilloedema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Papilloedema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Astigmatism		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Astigmatism	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Eye disorders	Astigmatism	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Astigmatism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye haemorrhage		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye haemorrhage	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Eye disorders	Eye haemorrhage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye haemorrhage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Hypermetropia		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Hypermetropia	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Eye disorders	Hypermetropia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Hypermetropia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Vernal keratoconjunctivitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Vernal keratoconjunctivitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Vernal keratoconjunctivitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Eye disorders	Vernal keratoconjunctivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Corneal epithelium defect		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Corneal epithelium defect	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Corneal epithelium defect	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Eye disorders	Corneal epithelium defect	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye pain		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye pain	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Eye pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Eye disorders	Vitreous opacities		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Vitreous opacities	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Vitreous opacities	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Vitreous opacities	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Eye disorders	Xerophthalmia		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							
Eye disorders	Xerophthalmia	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Xerophthalmia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Xerophthalmia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Musculoskel etal and connective tissue disorders			9.4% (5.5, 15.5)	5.5% (2.1, 13.7)	P=0.380 , I <sup>2</sup> =0%	P=0.032 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders		Mild	8.0% (4.5, 13.8)	5.5% (2.1, 13.7)	P=0.690 , I <sup>2</sup> =0%	P=0.032 , I <sup>2</sup> =0%	1.493 (0.456, 4.889)	1.450 (0.481, 4.371) 0.509	0.025 (-0.044 - 0.094)	P=0.264, I <sup>2</sup> =1997%	P=0.261, I <sup>2</sup> =2074%	P=0.291, I <sup>2</sup> =1041%	
Musculoskel etal and connective tissue disorders		Moderate	1.4% (0.4, 5.6)	0%	P=0.138 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.034)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Musculoskel etal and connective tissue disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Pain in extremity		3.6% (1.5, 8.4)	4.1% (1.3, 12.0)	P=0.288 , I <sup>2</sup> =0%	P=0.065 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Pain in extremity	Mild	2.9% (1.1, 7.5)	4.1% (1.3, 12.0)	P=0.471 , I <sup>2</sup> =0%	P=0.065 , I <sup>2</sup> =0%	0.690 (0.149, 3.192)	0.702 (0.163, 3.023) 0.635	-0.012 (-0.065 - 0.041)	P=0.520, I <sup>2</sup> =0%	P=0.525, I <sup>2</sup> =0%	P=0.380, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Musculoskeletal and connective tissue disorders	Pain in extremity	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders	Pain in extremity	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Musculoskeletal and connective tissue disorders	Arthralgia		4.3% (2.0, 9.3)	1.4% (0.2, 9.1)	P=0.655, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthralgia	Mild	4.3% (2.0, 9.3)	1.4% (0.2, 9.1)	P=0.655, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	3.276 (0.385, 27.880)	3.162 (0.390, 25.632) 0.281	0.030 (-0.013 - 0.073)	P=0.702, I <sup>2</sup> =0%	P=0.700, I <sup>2</sup> =0%	P=0.893, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders	Arthralgia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Musculoskeletal and connective tissue disorders	Arthralgia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Musculoskeletal pain		1.4% (0.4, 5.6)	0%	P=0.138, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck pain		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Musculoskeletal and connective tissue disorders	Neck pain	Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	0.519 (0.032, 8.512)	0.525 (0.034, 8.184) 0.646	-0.007 (-0.037 - 0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders	Neck pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Musculoskel etal and connective tissue disorders	Synovial cyst		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Synovial cyst	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Musculoskeletal and connective tissue disorders	Synovial cyst	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Synovial cyst	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthritis reactive		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Musculoskeletal and connective tissue disorders	Arthritis reactive	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders	Arthritis reactive	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthritis reactive	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Musculoskeletal and connective tissue disorders	Back pain		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Back pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Back pain	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Musculoskel etal and connective tissue disorders	Back pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Neck mass		0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Neck mass	Mild	0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Musculoskeletal and connective tissue disorders	Neck mass	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck mass	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Musculoskel etal and connective tissue disorders	Pain in jaw		0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Pain in jaw	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Pain in jaw	Moderate	0.7% (0.1, 5.0)	0%	P=0.295 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Musculoskeletal and connective tissue disorders	Pain in jaw	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Scoliosis		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Scoliosis	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Musculoskeletal and connective tissue disorders	Scoliosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Scoliosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders			4.3% (2.0, 9.3)	9.6% (4.6, 18.8)	P=0.033, I <sup>2</sup> =69.5%	P=0.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Metabolism and nutrition disorders		Mild	4.3% (2.0, 9.3)	9.6% (4.6, 18.8)	P=0.033, I <sup>2</sup> =69.5%	P=0.000, I <sup>2</sup> =0%	0.406 (0.126, 1.306)	0.457 (0.166, 1.263) 0.131	-0.052 (-0.125, 0.022)	P=0.363, I <sup>2</sup> =0%	P=0.402, I <sup>2</sup> =0%	P=0.004, I <sup>2</sup> =87.6%	
Metabolism and nutrition disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypertriglyceridaemia		2.9% (1.1, 7.5)	2.7% (0.7, 10.3)	P=0.008, I <sup>2</sup> =0%	P=0.061, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Metabolism and nutrition disorders	Hypertriglyceridaemia	Mild	2.9% (1.1, 7.5)	2.7% (0.7, 10.3)	P=0.008, I <sup>2</sup> =0%	P=0.061, I <sup>2</sup> =0%	1.074 (0.185, 6.220)	1.069 (0.207, 5.513) 0.936	0.002 (-0.044, 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Hypertriglyceridaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypertriglyceridaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Metabolism and nutrition disorders	Hypercholesterolaemia		0.7% (0.1, 5.0)	2.7% (0.7, 10.3)	P=0.187, I <sup>2</sup> =0%	P=0.061, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypercholesterolaemia	Mild	0.7% (0.1, 5.0)	2.7% (0.7, 10.3)	P=0.187, I <sup>2</sup> =0%	P=0.061, I <sup>2</sup> =0%	0.254 (0.022, 2.924)	0.267 (0.025, 2.832)	-0.020 (-0.060, 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Hypercholesterolaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypercholesterolaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Metabolism and nutrition disorders	Decreased appetite		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Decreased appetite	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Decreased appetite	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Metabolism and nutrition disorders	Decreased appetite	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperuricaemia		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperuricaemia	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Hyperuricaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Metabolism and nutrition disorders	Hyperuricaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Polydipsia		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Polydipsia	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Metabolism and nutrition disorders	Polydipsia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Polydipsia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Calcium deficiency		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Calcium deficiency	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Metabolism and nutrition disorders	Calcium deficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Calcium deficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperglycaemia		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Metabolism and nutrition disorders	Hyperglycaemia	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Hyperglycaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperglycaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperlipidaemia		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Metabolism and nutrition disorders	Hyperlipidaemia	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Hyperlipidaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperlipidaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Endocrine disorders			7.2% (3.9, 12.9)	8.2% (3.7, 17.1)	P=0.126, I <sup>2</sup> =49%	P=0.159, I <sup>2</sup> =36%							
Endocrine disorders		Mild	5.8% (2.9, 11.2)	8.2% (3.7, 17.1)	P=0.301, I <sup>2</sup> =0%	P=0.159, I <sup>2</sup> =36%	0.681 (0.225, 2.058)	0.703 (0.255, 1.934) 0.495	-0.024 (-0.098 - 0.049)	P=0.679, I <sup>2</sup> =0%	P=0.692, I <sup>2</sup> =0%	P=0.452, I <sup>2</sup> =0%	
Endocrine disorders		Moderate	1.4% (0.4, 5.6)	0%	P=0.138, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.034)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Endocrine disorders	Secondary hypothyroidism		4.3% (2.0, 9.3)	2.7% (0.7, 10.3)	P=0.009, I <sup>2</sup> =0%	P=0.133, I <sup>2</sup> =0%							
Endocrine disorders	Secondary hypothyroidism	Mild	3.6% (1.5, 8.4)	2.7% (0.7, 10.3)	P=0.018, I <sup>2</sup> =0%	P=0.133, I <sup>2</sup> =0%	1.333 (0.247, 7.184)	1.313 (0.266, 6.480) 0.739	0.009 (-0.040, 0.057)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Secondary hypothyroidism	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007, 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Secondary hypothyroidism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Endocrine disorders	Hypothyroidism		1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.061, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Endocrine disorders	Hypothyroidism	Mild	1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.061, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	1.062 (0.097, 11.654)	1.062 (0.097, 11.604) 0.96	0.001 (-0.033 - 0.034)	P=0.205, I <sup>2</sup> =3779%	P=0.207, I <sup>2</sup> =3728%	P=0.207, I <sup>2</sup> =3718%	
Endocrine disorders	Hypothyroidism	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Hypothyroidism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Diabetes insipidus		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Endocrine disorders	Diabetes insipidus	Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	0.519 (0.032, 8.512)	0.525 (0.034, 8.184) 0.646	-0.007 (-0.037 - 0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Diabetes insipidus	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Diabetes insipidus	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Secondary adrenocortical insufficiency		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Endocrine disorders	Secondary adrenocortical insufficiency	Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	0.519 (0.032, 8.512)	0.525 (0.034, 8.184) 0.646	-0.007 (-0.037 - 0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Secondary adrenocortical insufficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Secondary adrenocortical insufficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Adrenal insufficiency		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Endocrine disorders	Adrenal insufficiency	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Adrenal insufficiency	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Adrenal insufficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Precocious puberty		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Endocrine disorders	Precocious puberty	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Precocious puberty	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Precocious puberty	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders			5.1% (2.4, 10.3)	4.1% (1.3, 12.0)	P=0.964, I <sup>2</sup> =0%	P=0.741, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Blood and lymphatic system disorders		Mild	3.6% (1.5, 8.4)	4.1% (1.3, 12.0)	P=0.925, I <sup>2</sup> =0%	P=0.741, I <sup>2</sup> =0%	0.876 (0.203, 3.775)	0.881 (0.217, 3.581) 0.859	-0.005 (-0.060 - 0.050)	P=0.838, I <sup>2</sup> =0%	P=0.838, I <sup>2</sup> =0%	P=0.823, I <sup>2</sup> =0%	
Blood and lymphatic system disorders		Moderate	1.4% (0.4, 5.6)	0%	P=0.819, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.005 - 0.034)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.706, I <sup>2</sup> =0%	
Blood and lymphatic system disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Anaemia		0%	2.7% (0.7, 10.3)	P=1.000, I <sup>2</sup> =0%	P=0.828, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Blood and lymphatic system disorders	Anaemia	Mild	0%	2.7% (0.7, 10.3)	P=1.000, I <sup>2</sup> =0%	P=0.828, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.065 - 0.010)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.776, I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Blood and lymphatic system disorders	Iron deficiency anaemia		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Iron deficiency anaemia	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Iron deficiency anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Iron deficiency anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Blood and lymphatic system disorders	Lymphaden opathy		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphaden opathy	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Lymphaden opathy	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Blood and lymphatic system disorders	Lymphadenopathy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Neutropenia		1.4% (0.4, 5.6)	0%	P=0.138, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Neutropenia	Mild	1.4% (0.4, 5.6)	0%	P=0.138, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.034)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Neutropenia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Blood and lymphatic system disorders	Neutropenia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Blood and lymphatic system disorders	Lymphadenitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Granulocytopenia		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Granulocytopenia	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Blood and lymphatic system disorders	Granulocytopenia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Granulocytopenia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Hypochromic anaemia		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Blood and lymphatic system disorders	Hypochromic anaemia	Mild	0.7% (0.1, 5.0)	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Hypochromic anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Hypochromic anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Thymus disorder		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Blood and lymphatic system disorders	Thymus disorder	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Thymus disorder	Moderate	0.7% (0.1, 5.0)	0%	P=0.187 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Thymus disorder	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Immune system disorders			5.8% (2.9, 11.2)	2.7% (0.7, 10.3)	P=0.061 , I <sup>2</sup> =59.3 %	P=0.133 , I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Immune system disorders		Mild	5.1% (2.4, 10.3)	2.7% (0.7, 10.3)	P=0.103, I <sup>2</sup> =48.9%	P=0.133, I <sup>2</sup> =0%	1.909 (0.381, 9.573)	1.841 (0.398, 8.519) 0.435	0.023 (-0.029, 0.075)	P=0.830, I <sup>2</sup> =0%	P=0.833, I <sup>2</sup> =0%	P=0.650, I <sup>2</sup> =0%	
Immune system disorders		Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007, 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Immune system disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Seasonal allergy		2.9% (1.1, 7.5)	1.4% (0.2, 9.1)	P=0.035, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Immune system disorders	Seasonal allergy	Mild	2.9% (1.1, 7.5)	1.4% (0.2, 9.1)	P=0.035, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	2.158 (0.233, 19.948)	2.100 (0.242, 18.196) 0.501	0.015 (-0.023 - 0.053)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Immune system disorders	Seasonal allergy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Seasonal allergy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Hypersensitivity		0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Immune system disorders	Hypersensitivity	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Immune system disorders	Hypersensitivity	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Immune system disorders	Hypersensitivity	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Allergy to animal		1.4% (0.4, 5.6)	0%	P=0.138, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Immune system disorders	Allergy to animal	Mild	1.4% (0.4, 5.6)	0%	P=0.138, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.034)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Immune system disorders	Allergy to animal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Allergy to animal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Food allergy		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Immune system disorders	Food allergy	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Immune system disorders	Food allergy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Food allergy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders			2.2% (0.7, 6.5)	1.4% (0.2, 9.1)	P=0.021, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Reproductive system and breast disorders		Mild	2.2% (0.7, 6.5)	1.4% (0.2, 9.1)	P=0.021, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	1.594 (0.167, 15.160)	1.594 (0.167, 15.189) 0.685	0.008 (-0.028 - 0.045)	P=0.139, I <sup>2</sup> =543 9%	P=0.140, I <sup>2</sup> =539 8%	P=0.116, I <sup>2</sup> =594 9%	
Reproductive system and breast disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Penile adhesion		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Reproductive system and breast disorders	Penile adhesion	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Reproductive system and breast disorders	Penile adhesion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Penile adhesion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Reproductiv e system and breast disorders	Gynaecomasia		1.4% (0.4, 5.6)	0%	P=0.061 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Gynaecomasia	Mild	1.4% (0.4, 5.6)	0%	P=0.061 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.005 - 0.035)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Reproductiv e system and breast disorders	Gynaecomasia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Gynaecomasia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Reproductive system and breast disorders	Genital discomfort		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Genital discomfort	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Genital discomfort	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Reproductive system and breast disorders	Genital discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Balanoposthitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Balanoposthitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Balanoposthitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Reproductive system and breast disorders	Balanoposthitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Pelvic fluid collection		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Pelvic fluid collection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Reproductiv e system and breast disorders	Pelvic fluid collection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Pelvic fluid collection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Testicular appendage torsion		0.7% (0.1, 5.0)	0%	P=0.187 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Testicular appendage torsion	Mild	0.7% (0.1, 5.0)	0%	P=0.187 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Reproductive system and breast disorders	Testicular appendage torsion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Testicular appendage torsion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders			2.2% (0.7, 6.5)	0%	P=0.068, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Ear and labyrinth disorders		Mild	2.2% (0.7, 6.5)	0%	P=0.068, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.022 (-0.003 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Ear and labyrinth disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Ear pain		2.2% (0.7, 6.5)	0%	P=0.068, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Ear pain	Mild	2.2% (0.7, 6.5)	0%	P=0.068, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.022 (-0.003 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Ear and labyrinth disorders	Ear pain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Ear pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Cerumen impaction		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Cerumen impaction	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Ear and labyrinth disorders	Cerumen impaction	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Cerumen impaction	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Motion sickness		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Motion sickness	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Motion sickness	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Ear and labyrinth disorders	Motion sickness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders			1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.138, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Psychiatric disorders		Mild	0.7% (0.1, 5.0)	1.4% (0.2, 9.1)	P=0.295, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	0.519 (0.032, 8.512)	0.525 (0.034, 8.184) 0.646	-0.007 (-0.037 - 0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Psychiatric disorders		Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Psychiatric disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Attention deficit/hyperactivity disorder		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Psychiatric disorders	Attention deficit/hyperactivity disorder	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Psychiatric disorders	Attention deficit/hyperactivity disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Psychiatric disorders	Attention deficit/hyperactivity disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Enuresis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Enuresis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Enuresis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Enuresis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Psychiatric disorders	Affect lability		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Affect lability	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Psychiatric disorders	Affect lability	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Affect lability	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Psychiatric disorders	Depressive symptom		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Depressive symptom	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Depressive symptom	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Psychiatric disorders	Depressive symptom	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.138, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Mild	1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.138, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	1.051 (0.093, 11.942)	1.050 (0.098, 11.246) 0.968	0.001 (-0.032 - 0.034)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma		1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.138 , I <sup>2</sup> =0%	P=0.291 , I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Mild	1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.138 , I <sup>2</sup> =0%	P=0.291 , I <sup>2</sup> =0%	1.051 (0.093, 11.942)	1.050 (0.098, 11.246) 0.968	0.001 (-0.032 - 0.034)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders			2.2% (0.7, 6.5)	0%	P=0.755 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Cardiac disorders		Mild	1.4% (0.4, 5.6)	0%	P=0.819, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.005 - 0.034)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.706, I <sup>2</sup> =0%	
Cardiac disorders		Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Cardiac disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinoatrial block		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Cardiac disorders	Sinoatrial block	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Cardiac disorders	Sinoatrial block	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinoatrial block	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinus tachycardia		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinus tachycardia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Cardiac disorders	Sinus tachycardia	Moderate	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Cardiac disorders	Sinus tachycardia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Tachycardia		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Tachycardia	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Cardiac disorders	Tachycardia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Tachycardia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Myocarditis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Myocarditis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Cardiac disorders	Myocarditis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Myocarditis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Wandering pacemaker		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Wandering pacemaker	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Cardiac disorders	Wandering pacemaker	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Cardiac disorders	Wandering pacemaker	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders			1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.138, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							
Renal and urinary disorders		Mild	1.4% (0.4, 5.6)	1.4% (0.2, 9.1)	P=0.138, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	1.057 (0.095, 11.706)	1.057 (0.095, 11.765) 0.964	0.001 (-0.033 - 0.034)	P=0.211, I <sup>2</sup> =360 0%	P=0.213, I <sup>2</sup> =354 5%	P=0.216, I <sup>2</sup> =347 6%	
Renal and urinary disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Renal and urinary disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Pollakiuria		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Pollakiuria	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Renal and urinary disorders	Pollakiuria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Renal and urinary disorders	Pollakiuria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Polyuria		0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Polyuria	Mild	0.7% (0.1, 5.0)	0%	P=0.295, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Renal and urinary disorders	Polyuria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Polyuria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Renal and urinary disorders	Nocturia		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%							
Renal and urinary disorders	Nocturia	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Renal and urinary disorders	Nocturia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Nocturia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Vascular disorders			2.2% (0.7, 6.5)	0%	P=0.755, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders		Mild	2.2% (0.7, 6.5)	0%	P=0.755, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.022 (-0.003 - 0.046)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.682, I <sup>2</sup> =0%	
Vascular disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Vascular disorders	Hypotension		1.4% (0.4, 5.6)	0%	P=0.138, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Hypotension	Mild	1.4% (0.4, 5.6)	0%	P=0.138, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.034)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Vascular disorders	Hypotension	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Hypotension	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Cyanosis		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Vascular disorders	Cyanosis	Mild	0.7% (0.1, 5.0)	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Vascular disorders	Cyanosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Cyanosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders			1.4% (0.4, 5.6)	0%	P=0.061, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Congenital, familial and genetic disorders		Mild	1.4% (0.4, 5.6)	0%	P=0.061, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.015 (-0.005 - 0.035)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Congenital, familial and genetic disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Age ≥ 6 years													
Congenital, familial and genetic disorders	Buried penis syndrome		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Buried penis syndrome	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Congenital, familial and genetic disorders	Buried penis syndrome	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Buried penis syndrome	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Congenital, familial and genetic disorders	Supernumerary teeth		0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Supernumerary teeth	Mild	0.7% (0.1, 5.0)	0%	P=0.187, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Congenital, familial and genetic disorders	Supernumerary teeth	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Congenital, familial and genetic disorders	Supernumerary teeth	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders			0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							
Hepatobiliary disorders		Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Hepatobiliary disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Hepatobiliary disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders	Hepatomegaly		0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%							

Table 1.18.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by age

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years													
Hepatobiliary disorders	Hepatomegaly	Mild	0%	1.4% (0.2, 9.1)	P=1.000, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.014 (-0.040 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Hepatobiliary disorders	Hepatomegaly	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders	Hepatomegaly	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.													

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Any adverse event			87.9% (82.1, 92.0)	83.5% (74.4, 89.8)	P=0.000, I <sup>2</sup> =0%	P=0.001, I <sup>2</sup> =86%							P=0.868
Any adverse event		Mild	70.5% (63.3, 76.8)	60.4% (50.1, 69.9)	P=0.000, I <sup>2</sup> =96.5%	P=0.000, I <sup>2</sup> =95%	1.764 (0.952, 3.267)	1.160 (0.979, 1.375) 0.086	0.097 (-0.009, 0.203)	P=0.759, I <sup>2</sup> =0%	P=0.076, I <sup>2</sup> =6820%	P=0.260, I <sup>2</sup> =2104%	P=0.500
Any adverse event		Moderate	15.6% (10.9, 21.8)	23.1% (15.6, 32.8)	P=0.001, I <sup>2</sup> =88.8%	P=0.001, I <sup>2</sup> =89%	0.598 (0.307, 1.165)	0.683 (0.419, 1.113) 0.126	-0.073 (-0.171, 0.025)	P=0.682, I <sup>2</sup> =0%	P=0.811, I <sup>2</sup> =0%	P=0.222, I <sup>2</sup> =3282%	P=0.208

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Any adverse event		Severe	1.7% (0.6, 5.2)	0%	P=0.563, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.017 (-0.002 - 0.037)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.602, I <sup>2</sup> =0%	P=0.481
Infections and infestations			56.6% (49.2, 63.8)	61.5% (51.2, 70.9)	P=0.147, I <sup>2</sup> =52.1%	P=0.573, I <sup>2</sup> =0%							P=0.870
Infections and infestations		Mild	48.0% (40.6, 55.4)	45.1% (35.2, 55.3)	P=0.005, I <sup>2</sup> =87.2%	P=0.015, I <sup>2</sup> =82%	1.123 (0.665, 1.896)	1.061 (0.812, 1.386) 0.667	0.027 (-0.096 - 0.150)	P=0.754, I <sup>2</sup> =0%	P=0.686, I <sup>2</sup> =0%	P=0.764, I <sup>2</sup> =0%	P=0.161
Infections and infestations		Moderate	6.9% (4.0, 11.8)	16.5% (10.2, 25.6)	P=0.001, I <sup>2</sup> =82.6%	P=0.010, I <sup>2</sup> =82%	0.359 (0.155, 0.830)	0.426 (0.213, 0.851) 0.016	-0.094 (-0.177 - -0.011)	P=0.456, I <sup>2</sup> =0%	P=0.380, I <sup>2</sup> =0%	P=0.257, I <sup>2</sup> =2205%	P=0.069



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations		Severe	1.7% (0.6, 5.2)	0%	P=0.563, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.017 (-0.002 - 0.037)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.602, I <sup>2</sup> =0%	P=0.481
Infections and infestations	Upper respiratory tract infection		26.0% (20.0, 33.1)	33.0% (24.1, 43.2)	P=0.000, I <sup>2</sup> =96%	P=0.000, I <sup>2</sup> =94%							P=0.582
Infections and infestations	Upper respiratory tract infection	Mild	26.0% (20.0, 33.1)	27.5% (19.3, 37.5)	P=0.000, I <sup>2</sup> =96%	P=0.000, I <sup>2</sup> =94%	0.891 (0.469, 1.694)	0.935 (0.645, 1.356) 0.724	-0.018 (-0.118 - 0.083)	P=0.774, I <sup>2</sup> =0%	P=0.825, I <sup>2</sup> =0%	P=0.581, I <sup>2</sup> =0%	P=0.379

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Upper respiratory tract infection	Moderate	0%	5.5% (2.3, 12.5)	P=1.000, I <sup>2</sup> =0%	P=0.626, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.055 (-0.102 - -0.008)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.655, I <sup>2</sup> =0%	P=0.280
Infections and infestations	Upper respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Nasopharyngitis		7.5% (4.4, 12.5)	11.0% (6.0, 19.2)	P=0.006, I <sup>2</sup> =81.6%	P=0.186, I <sup>2</sup> =38%							P=0.542
Infections and infestations	Nasopharyngitis	Mild	6.9% (4.0, 11.8)	8.8% (4.5, 16.6)	P=0.012, I <sup>2</sup> =78.9%	P=0.139, I <sup>2</sup> =48%	0.776 (0.301, 2.001)	0.797 (0.342, 1.855) 0.599	-0.018 (-0.086 - 0.051)	P=0.634, I <sup>2</sup> =0%	P=0.619, I <sup>2</sup> =0%	P=0.903, I <sup>2</sup> =0%	P=0.471

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Nasopharyngitis	Moderate	0.6% (0.1, 4.0)	2.2% (0.6, 8.4)	P=0.236, I <sup>2</sup> =0%	P=0.987, I <sup>2</sup> =0%	0.262 (0.023, 2.918)	0.266 (0.025, 2.862) 0.275	-0.016 (-0.048, 0.016)	P=0.575, I <sup>2</sup> =0%	P=0.574, I <sup>2</sup> =0%	P=0.642, I <sup>2</sup> =0%	P=0.737
Infections and infestations	Nasopharyngitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Pharyngitis		4.0% (1.9, 8.2)	11.0% (6.0, 19.2)	P=0.041, I <sup>2</sup> =65.7%	P=0.005, I <sup>2</sup> =79%							P=0.296
Infections and infestations	Pharyngitis	Mild	4.0% (1.9, 8.2)	11.0% (6.0, 19.2)	P=0.041, I <sup>2</sup> =65.7%	P=0.005, I <sup>2</sup> =79%	0.330 (0.119, 0.919)	0.373 (0.150, 0.929) 0.034	-0.069 (-0.138, 0.001)	P=0.741, I <sup>2</sup> =0%	P=0.802, I <sup>2</sup> =0%	P=0.012, I <sup>2</sup> =839%	P=0.426

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Pharyngitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.686
Infections and infestations	Pharyngitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Infections and infestations	Respiratory tract infection		5.8% (3.1, 10.4)	5.5% (2.3, 12.5)	P=0.985 , I <sup>2</sup> =0%	P=0.663 , I <sup>2</sup> =0%							P=0.838
Infections and infestations	Respiratory tract infection	Mild	5.2% (2.7, 9.7)	4.4% (1.7, 11.1)	P=0.745 , I <sup>2</sup> =0%	P=0.982 , I <sup>2</sup> =0%	1.192 (0.357, 3.983)	1.182 (0.374, 3.735)	0.008 (-0.046 - 0.062)	P=0.871, I <sup>2</sup> =0%	P=0.872, I <sup>2</sup> =0%	P=0.855, I <sup>2</sup> =0%	P=0.583

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Respiratory tract infection	Moderate	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	0.529 (0.032, 8.665)	0.535 (0.034, 8.355) 0.655	-0.005 (-0.029, 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.652
Infections and infestations	Respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Bronchitis		6.4% (3.6, 11.1)	4.4% (1.7, 11.1)	P=0.117, I <sup>2</sup> =54.5%	P=0.982, I <sup>2</sup> =0%							P=0.508
Infections and infestations	Bronchitis	Mild	4.6% (2.3, 9.0)	2.2% (0.6, 8.4)	P=0.143, I <sup>2</sup> =46.4%	P=0.091, I <sup>2</sup> =0%	2.160 (0.443, 10.526)	2.080 (0.457, 9.467) 0.343	0.024 (-0.019, 0.067)	P=0.692, I <sup>2</sup> =0%	P=0.685, I <sup>2</sup> =0%	P=0.804, I <sup>2</sup> =0%	P=0.783

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Bronchitis	Moderate	1.2% (0.3, 4.5)	2.2% (0.6, 8.4)	P=0.993, I <sup>2</sup> =0%	P=0.096, I <sup>2</sup> =0%	0.524 (0.072, 3.785)	0.529 (0.075, 3.725) 0.523	-0.010 (-0.044 - 0.024)	P=0.379, I <sup>2</sup> =0%	P=0.382, I <sup>2</sup> =0%	P=0.297, I <sup>2</sup> =802%	P=0.745
Infections and infestations	Bronchitis	Severe	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Infections and infestations	Tonsillitis		4.0% (1.9, 8.2)	5.5% (2.3, 12.5)	P=0.044, I <sup>2</sup> =64.8%	P=0.147, I <sup>2</sup> =41%							P=0.891
Infections and infestations	Tonsillitis	Mild	4.0% (1.9, 8.2)	4.4% (1.7, 11.1)	P=0.044, I <sup>2</sup> =64.8%	P=0.016, I <sup>2</sup> =0%	0.901 (0.252, 3.226)	0.908 (0.279, 2.959) 0.873	-0.004 (-0.055 - 0.047)	P=0.659, I <sup>2</sup> =0%	P=0.661, I <sup>2</sup> =0%	P=0.542, I <sup>2</sup> =0%	P=0.811

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Tonsillitis	Moderate	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.681
Infections and infestations	Tonsillitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Rhinitis		2.9% (1.2, 6.8)	3.3% (1.1, 9.7)	P=0.640, I <sup>2</sup> =0%	P=0.566, I <sup>2</sup> =0%							P=0.858
Infections and infestations	Rhinitis	Mild	2.9% (1.2, 6.8)	3.3% (1.1, 9.7)	P=0.640, I <sup>2</sup> =0%	P=0.566, I <sup>2</sup> =0%	0.876 (0.204, 3.760)	0.880 (0.215, 3.598) 0.859	-0.004 (-0.048 - 0.040)	P=0.865, I <sup>2</sup> =0%	P=0.866, I <sup>2</sup> =0%	P=0.829, I <sup>2</sup> =0%	P=0.858

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Rhinitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Rhinitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Gastroenteritis		1.7% (0.6, 5.2)	3.3% (1.1, 9.7)	P=0.550, I <sup>2</sup> =0%	P=0.566, I <sup>2</sup> =0%							P=0.766
Infections and infestations	Gastroenteritis	Mild	1.7% (0.6, 5.2)	2.2% (0.6, 8.4)	P=0.550, I <sup>2</sup> =0%	P=0.987, I <sup>2</sup> =0%	0.788 (0.129, 4.799)	0.792 (0.135, 4.643)	-0.005 (-0.040, 0.031)	P=0.695, I <sup>2</sup> =0%	P=0.695, I <sup>2</sup> =0%	P=0.737, I <sup>2</sup> =0%	P=0.570



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Gastroenteritis	Moderate	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.681
Infections and infestations	Gastroenteritis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Pharyngitis streptococcal		1.7% (0.6, 5.2)	3.3% (1.1, 9.7)	P=0.039, I <sup>2</sup> =0%	P=0.041, I <sup>2</sup> =0%							P=0.693
Infections and infestations	Pharyngitis streptococcal	Mild	1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.093, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	1.071 (0.095, 12.141)	1.070 (0.100, 11.485) 0.956	0.001 (-0.026 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.506

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Pharyngitis streptococcal	Moderate	0.6% (0.1, 4.0)	2.2% (0.6, 8.4)	P=0.236, I <sup>2</sup> =0%	P=0.096, I <sup>2</sup> =0%	0.259 (0.023, 2.934)	0.267 (0.025, 2.871) 0.276	-0.016 (-0.048, 0.016)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.721
Infections and infestations	Pharyngitis streptococcal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Sinusitis		2.3% (0.9, 6.0)	2.2% (0.6, 8.4)	P=0.296, I <sup>2</sup> =0%	P=0.987, I <sup>2</sup> =0%							P=0.422
Infections and infestations	Sinusitis	Mild	1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.993, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	1.059 (0.094, 11.892)	1.058 (0.096, 11.617) 0.963	0.001 (-0.026, 0.027)	P=0.587, I <sup>2</sup> =0%	P=0.587, I <sup>2</sup> =0%	P=0.606, I <sup>2</sup> =0%	P=0.526

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Sinusitis	Moderate	1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.093, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	1.057 (0.097, 11.555)	1.057 (0.098, 11.454) 0.963	0.001 (-0.026, 0.028)	P=0.204, I <sup>2</sup> =381 5%	P=0.205, I <sup>2</sup> =377 4%	P=0.210, I <sup>2</sup> =364 1%	P=0.904
Infections and infestations	Sinusitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Pneumonia		1.2% (0.3, 4.5)	4.4% (1.7, 11.1)	P=0.096, I <sup>2</sup> =0%	P=0.982, I <sup>2</sup> =0%							P=0.404
Infections and infestations	Pneumonia	Mild	1.2% (0.3, 4.5)	2.2% (0.6, 8.4)	P=0.096, I <sup>2</sup> =0%	P=0.091, I <sup>2</sup> =0%	0.506 (0.069, 3.716)	0.517 (0.075, 3.552) 0.502	-0.011 (-0.045, 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.936

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Pneumonia	Moderate	0%	2.2% (0.6, 8.4)	P=1.000, I <sup>2</sup> =0%	P=0.096, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.022 (-0.052 - 0.008)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.309
Infections and infestations	Pneumonia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Ear infection		2.3% (0.9, 6.0)	0%	P=0.017, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.402
Infections and infestations	Ear infection	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.486

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Ear infection	Moderate	1.7% (0.6, 5.2)	0%	P=0.039, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.018 (-0.002 - 0.037)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.777
Infections and infestations	Ear infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Viral infection		1.7% (0.6, 5.2)	0%	P=0.039, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.957
Infections and infestations	Viral infection	Mild	1.7% (0.6, 5.2)	0%	P=0.039, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.018 (-0.002 - 0.037)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.933

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Viral infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686
Infections and infestations	Viral infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Respiratory tract infection viral		1.7% (0.6, 5.2)	2.2% (0.6, 8.4)	P=0.039, I <sup>2</sup> =0%	P=0.096, I <sup>2</sup> =0%							P=0.888
Infections and infestations	Respiratory tract infection viral	Mild	1.2% (0.3, 4.5)	2.2% (0.6, 8.4)	P=0.093, I <sup>2</sup> =0%	P=0.096, I <sup>2</sup> =0%	0.524 (0.071, 3.846)	0.535 (0.078, 3.674) 0.525	-0.010 (-0.044, 0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.946

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Respiratory tract infection viral	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Infections and infestations	Respiratory tract infection viral	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Gastroenteritis viral		1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.093, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.796
Infections and infestations	Gastroenteritis viral	Mild	1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.093, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	1.057 (0.097, 11.555)	1.057 (0.098, 11.454) 0.963	0.001 (-0.026 - 0.028)	P=0.204, I <sup>2</sup> =3815%	P=0.205, I <sup>2</sup> =3774%	P=0.210, I <sup>2</sup> =3641%	P=0.796

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Gastroenteritis viral	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Gastroenteritis viral	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Otitis media acute		1.2% (0.3, 4.5)	2.2% (0.6, 8.4)	P=0.993, I <sup>2</sup> =0%	P=0.987, I <sup>2</sup> =0%							P=0.942
Infections and infestations	Otitis media acute	Mild	1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.993, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	1.047 (0.094, 11.646)	1.046 (0.097, 11.279)	0.001 (-0.026 - 0.027)	P=0.569, I <sup>2</sup> =0%	P=0.569, I <sup>2</sup> =0%	P=0.587, I <sup>2</sup> =0%	P=0.842



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Otitis media acute	Moderate	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.681
Infections and infestations	Otitis media acute	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Varicella		1.7% (0.6, 5.2)	1.1% (0.2, 7.4)	P=0.550, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.724
Infections and infestations	Varicella	Mild	1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.993, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	1.047 (0.094, 11.646)	1.046 (0.097, 11.279) 0.97	0.001 (-0.026 - 0.027)	P=0.569, I <sup>2</sup> =0%	P=0.569, I <sup>2</sup> =0%	P=0.587, I <sup>2</sup> =0%	P=0.842

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Varicella	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Infections and infestations	Varicella	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Conjunctivitis		1.2% (0.3, 4.5)	0%	P=0.993, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.535
Infections and infestations	Conjunctivitis	Mild	1.2% (0.3, 4.5)	0%	P=0.993, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.012 (-0.004 - 0.027)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.721, I <sup>2</sup> =0%	P=0.330

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Conjunctivitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686
Infections and infestations	Conjunctivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Enteritis infectious		0.6% (0.1, 4.0)	2.2% (0.6, 8.4)	P=0.236, I <sup>2</sup> =0%	P=0.096, I <sup>2</sup> =0%							P=0.721
Infections and infestations	Enteritis infectious	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Enteritis infectious	Moderate	0%	2.2% (0.6, 8.4)	P=1.000, I <sup>2</sup> =0%	P=0.096, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.022 (-0.052 - 0.008)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.545
Infections and infestations	Enteritis infectious	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Influenza		0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.635
Infections and infestations	Influenza	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.681

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Influenza	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.939
Infections and infestations	Influenza	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Enterobiasis		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.310
Infections and infestations	Enterobiasis	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.310
Infections and infestations	Enterobiasis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Enterobiasis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Herpangina		1.7% (0.6, 5.2)	0%	P=0.041, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.540
Infections and infestations	Herpangina	Mild	1.7% (0.6, 5.2)	0%	P=0.041, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.017 (-0.002 - 0.037)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.540
Infections and infestations	Herpangina	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Herpangina	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Otitis media		1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.096, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.827
Infections and infestations	Otitis media	Mild	1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.096, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	1.035 (0.091, 11.735)	1.034 (0.096, 11.103) 0.978	0.000 (-0.026 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.827
Infections and infestations	Otitis media	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Otitis media	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Periodontitis		1.7% (0.6, 5.2)	0%	P=0.041, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.540
Infections and infestations	Periodontitis	Mild	1.7% (0.6, 5.2)	0%	P=0.041, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.017 (-0.002 - 0.037)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.540
Infections and infestations	Periodontitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Periodontitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Helminthic infection		0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.949
Infections and infestations	Helminthic infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Helminthic infection	Moderate	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	0.529 (0.032, 8.665)	0.535 (0.034, 8.355) 0.655	-0.005 (-0.029 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.949
Infections and infestations	Helminthic infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Pulpitis dental		1.2% (0.3, 4.5)	0%	P=0.993, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.584
Infections and infestations	Pulpitis dental	Mild	1.2% (0.3, 4.5)	0%	P=0.993, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.012 (-0.004 - 0.027)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.721, I <sup>2</sup> =0%	P=0.584
Infections and infestations	Pulpitis dental	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Pulpitis dental	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Viral upper respiratory tract infection		0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.486
Infections and infestations	Viral upper respiratory tract infection	Mild	0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.486
Infections and infestations	Viral upper respiratory tract infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Infections and infestations	Viral upper respiratory tract infection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Hordeolum		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.488
Infections and infestations	Hordeolum	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.488
Infections and infestations	Hordeolum	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Hordeolum	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Pharyngoton sillitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.975
Infections and infestations	Pharyngoton sillitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.763
Infections and infestations	Pharyngoton sillitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.686
Infections and infestations	Pharyngoton sillitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Infections and infestations	Urinary tract infection		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.584

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Urinary tract infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.773
Infections and infestations	Urinary tract infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.763
Infections and infestations	Urinary tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Hand-foot-and-mouth disease		1.2% (0.3, 4.5)	0%	P=0.096, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.629

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Hand-foot-and-mouth disease	Mild	1.2% (0.3, 4.5)	0%	P=0.096, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.011 (-0.004 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.629
Infections and infestations	Hand-foot-and-mouth disease	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Hand-foot-and-mouth disease	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Laryngitis		0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.240, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.944

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Laryngitis	Mild	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.240, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	0.512 (0.031, 8.376)	0.517 (0.033, 8.078) 0.638	-0.005 (-0.029 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.944
Infections and infestations	Laryngitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Laryngitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Oral herpes		0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.240, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.944
Infections and infestations	Oral herpes	Mild	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.240, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	0.512 (0.031, 8.376)	0.517 (0.033, 8.078) 0.638	-0.005 (-0.029 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.944



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Oral herpes	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Infections and infestations	Oral herpes	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Infections and infestations	Appendicitis		0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.769
Infections and infestations	Appendicitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Appendicitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Appendicitis	Severe	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Infections and infestations	Atypical pneumonia		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769
Infections and infestations	Atypical pneumonia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Atypical pneumonia	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Infections and infestations	Atypical pneumonia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Conjunctivitis bacterial		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.681
Infections and infestations	Conjunctivitis bacterial	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.681
Infections and infestations	Conjunctivitis bacterial	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Conjunctivitis bacterial	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Laryngitis viral		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.681
Infections and infestations	Laryngitis viral	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.681
Infections and infestations	Laryngitis viral	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Laryngitis viral	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Molluscum contagiosum		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769
Infections and infestations	Molluscum contagiosum	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Infections and infestations	Molluscum contagiosum	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Molluscum contagiosum	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Otitis externa		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769
Infections and infestations	Otitis externa	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Otitis externa	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Infections and infestations	Otitis externa	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Rotavirus infection		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769
Infections and infestations	Rotavirus infection	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Infections and infestations	Rotavirus infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Rotavirus infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Tinea pedis		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769
Infections and infestations	Tinea pedis	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Infections and infestations	Tinea pedis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Tinea pedis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Tooth abscess		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769
Infections and infestations	Tooth abscess	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Infections and infestations	Tooth abscess	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Tooth abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Croup infectious		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.660

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Croup infectious	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Croup infectious	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Croup infectious	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Cystitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Cystitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.686
Infections and infestations	Cystitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Infections and infestations	Cystitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Infections and infestations	Eczema infected		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.686
Infections and infestations	Eczema infected	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.686

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Eczema infected	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Infections and infestations	Eczema infected	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Infections and infestations	Infected bite		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.686
Infections and infestations	Infected bite	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.686
Infections and infestations	Infected bite	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Infected bite	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Infections and infestations	Vulvitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.686
Infections and infestations	Vulvitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.686
Infections and infestations	Vulvitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Vulvitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Abscess limb		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771
Infections and infestations	Abscess limb	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Infections and infestations	Abscess limb	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Abscess limb	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Bacterial infection		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.678
Infections and infestations	Bacterial infection	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678
Infections and infestations	Bacterial infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Bacterial infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Chronic tonsillitis		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771
Infections and infestations	Chronic tonsillitis	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Infections and infestations	Chronic tonsillitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Chronic tonsillitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Folliculitis		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771
Infections and infestations	Folliculitis	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Infections and infestations	Folliculitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Folliculitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Gastrointestinal bacterial infection		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Gastrointestinal bacterial infection	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Infections and infestations	Gastrointestinal bacterial infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Gastrointestinal bacterial infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Herpes virus infection		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.678

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Herpes virus infection	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678
Infections and infestations	Herpes virus infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Herpes virus infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Infectious mononucleosis		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.678

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Infectious mononucleosis	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678
Infections and infestations	Infectious mononucleosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Infectious mononucleosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Mumps		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Mumps	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Infections and infestations	Mumps	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Mumps	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Myringitis		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771
Infections and infestations	Myringitis	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Myringitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Myringitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Peritonsillar abscess		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.678
Infections and infestations	Peritonsillar abscess	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Peritonsillar abscess	Moderate	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678
Infections and infestations	Peritonsillar abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Sinobronchitis		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.678
Infections and infestations	Sinobronchitis	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Sinobronchitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Sinobronchitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Subcutaneous abscess		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771
Infections and infestations	Subcutaneous abscess	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Subcutaneous abscess	Moderate	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Infections and infestations	Subcutaneous abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Tonsillitis bacterial		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771
Infections and infestations	Tonsillitis bacterial	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Infections and infestations	Tonsillitis bacterial	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Tonsillitis bacterial	Severe	0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.771
Infections and infestations	Tracheitis		0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.771
Infections and infestations	Tracheitis	Mild	0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.771
Infections and infestations	Tracheitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Infections and infestations	Tracheitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Infections and infestations	Chronic sinusitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.670
Infections and infestations	Chronic sinusitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.670
Infections and infestations	Chronic sinusitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Infections and infestations	Chronic sinusitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations			30.1% (23.7, 37.3)	29.7% (21.2, 39.8)	P=0.000, I <sup>2</sup> =97%	P=0.000, I <sup>2</sup> =94%							P=0.415
Investigations		Mild	30.1% (23.7, 37.3)	29.7% (21.2, 39.8)	P=0.000, I <sup>2</sup> =97%	P=0.000, I <sup>2</sup> =94%	0.998 (0.516, 1.933)	0.999 (0.721, 1.386) 0.996	0.000 (-0.098, 0.097)	P=0.693, I <sup>2</sup> =0%	P=0.695, I <sup>2</sup> =0%	P=0.679, I <sup>2</sup> =0%	P=0.415
Investigations		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Blood glucose increased		9.8% (6.2, 15.2)	15.4% (9.3, 24.3)	P=0.000, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%							P=0.220
Investigations	Blood glucose increased	Mild	9.8% (6.2, 15.2)	15.4% (9.3, 24.3)	P=0.000, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%	0.538 (0.236, 1.226)	0.628 (0.342, 1.155) 0.134	-0.058 (-0.138, 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.220
Investigations	Blood glucose increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood glucose increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Insulin-like growth factor increased		16.2% (11.4, 22.4)	2.2% (0.6, 8.4)	P=0.000, I <sup>2</sup> =93.2%	P=0.091, I <sup>2</sup> =0%							P=0.216
Investigations	Insulin-like growth factor increased	Mild	16.2% (11.4, 22.4)	2.2% (0.6, 8.4)	P=0.000, I <sup>2</sup> =93.2%	P=0.091, I <sup>2</sup> =0%	9.918 (2.231, 44.085)	7.253 (1.804, 29.160) 0.005	0.138 (0.077 - 0.199)	P=0.407, I <sup>2</sup> =0%	P=0.515, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =96.72%	P=0.216
Investigations	Insulin-like growth factor increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Insulin-like growth factor increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Low density lipoprotein increased		2.3% (0.9, 6.0)	4.4% (1.7, 11.1)	P=0.018, I <sup>2</sup> =0%	P=0.016, I <sup>2</sup> =0%							P=0.929
Investigations	Low density lipoprotein increased	Mild	2.3% (0.9, 6.0)	4.4% (1.7, 11.1)	P=0.018, I <sup>2</sup> =0%	P=0.016, I <sup>2</sup> =0%	0.494 (0.118, 2.076)	0.517 (0.136, 1.972) 0.334	-0.021 (-0.068, 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.929
Investigations	Low density lipoprotein increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Low density lipoprotein increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood alkaline phosphatase increased		1.7% (0.6, 5.2)	4.4% (1.7, 11.1)	P=0.041, I <sup>2</sup> =0%	P=0.016, I <sup>2</sup> =0%							P=0.803
Investigations	Blood alkaline phosphatase increased	Mild	1.7% (0.6, 5.2)	4.4% (1.7, 11.1)	P=0.041, I <sup>2</sup> =0%	P=0.016, I <sup>2</sup> =0%	0.366 (0.078, 1.712)	0.388 (0.091, 1.659) 0.202	-0.027 (-0.073, 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.803
Investigations	Blood alkaline phosphatase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Blood alkaline phosphatase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Eosinophil count increased		2.3% (0.9, 6.0)	1.1% (0.2, 7.4)	P=0.306, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.832
Investigations	Eosinophil count increased	Mild	2.3% (0.9, 6.0)	1.1% (0.2, 7.4)	P=0.306, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	2.119 (0.232, 19.393)	2.080 (0.239, 18.137) 0.507	0.012 (-0.019 - 0.043)	P=0.763, I <sup>2</sup> =0%	P=0.764, I <sup>2</sup> =0%	P=0.794, I <sup>2</sup> =0%	P=0.832
Investigations	Eosinophil count increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Eosinophil count increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood iron increased		1.2% (0.3, 4.5)	3.3% (1.1, 9.7)	P=0.096, I <sup>2</sup> =0%	P=0.541, I <sup>2</sup> =0%							P=0.794
Investigations	Blood iron increased	Mild	1.2% (0.3, 4.5)	3.3% (1.1, 9.7)	P=0.096, I <sup>2</sup> =0%	P=0.541, I <sup>2</sup> =0%	0.336 (0.054, 2.075)	0.346 (0.059, 2.033) 0.24	-0.022 (-0.061 - 0.018)	P=0.573, I <sup>2</sup> =0%	P=0.566, I <sup>2</sup> =0%	P=0.865, I <sup>2</sup> =0%	P=0.794
Investigations	Blood iron increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Blood iron increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Alanine aminotransferase increased		1.7% (0.6, 5.2)	1.1% (0.2, 7.4)	P=0.041, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.384
Investigations	Alanine aminotransferase increased	Mild	1.7% (0.6, 5.2)	1.1% (0.2, 7.4)	P=0.041, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	1.571 (0.159, 15.555)	1.552 (0.166, 14.494) 0.7	0.006 (-0.023 - 0.035)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.384
Investigations	Alanine aminotransferase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Alanine aminotransferase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Blood phosphorus increased		2.3% (0.9, 6.0)	1.1% (0.2, 7.4)	P=0.018, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.581
Investigations	Blood phosphorus increased	Mild	2.3% (0.9, 6.0)	1.1% (0.2, 7.4)	P=0.018, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	2.120 (0.230, 19.555)	2.069 (0.238, 17.968) 0.51	0.012 (-0.019, 0.042)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.581
Investigations	Blood phosphorus increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood phosphorus increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Blood uric acid increased		1.7% (0.6, 5.2)	2.2% (0.6, 8.4)	P=0.041, I <sup>2</sup> =0%	P=0.091, I <sup>2</sup> =0%							P=0.899
Investigations	Blood uric acid increased	Mild	1.7% (0.6, 5.2)	2.2% (0.6, 8.4)	P=0.041, I <sup>2</sup> =0%	P=0.091, I <sup>2</sup> =0%	0.768 (0.124, 4.770)	0.776 (0.134, 4.477) 0.777	-0.005 (-0.040, 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.899
Investigations	Blood uric acid increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood uric acid increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Cortisol decreased		1.2% (0.3, 4.5)	0%	P=0.096, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.587
Investigations	Cortisol decreased	Mild	1.2% (0.3, 4.5)	0%	P=0.096, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.011 (-0.004 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.587
Investigations	Cortisol decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Cortisol decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Aspartate aminotransferase increased		1.2% (0.3, 4.5)	0%	P=0.096, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.365

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Aspartate aminotransferase increased	Mild	1.2% (0.3, 4.5)	0%	P=0.096, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.011 (-0.004 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.365
Investigations	Aspartate aminotransferase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Aspartate aminotransferase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood triglycerides increased		1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.096, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.827

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Blood triglycerides increased	Mild	1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.096, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	1.035 (0.091, 11.735)	1.034 (0.096, 11.103) 0.978	0.000 (-0.026 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.827
Investigations	Blood triglycerides increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood triglycerides increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood glucose abnormal		0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.240, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.754



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Blood glucose abnormal	Mild	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.240, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	0.512 (0.031, 8.376)	0.517 (0.033, 8.078) 0.638	-0.005 (-0.029, 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.754
Investigations	Blood glucose abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood glucose abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood thyroid stimulating hormone increased		1.2% (0.3, 4.5)	0%	P=0.993, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.584

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Blood thyroid stimulating hormone increased	Mild	1.2% (0.3, 4.5)	0%	P=0.993, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.012 (-0.004 - 0.027)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.721, I <sup>2</sup> =0%	P=0.584
Investigations	Blood thyroid stimulating hormone increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood thyroid stimulating hormone increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	White blood cell count decreased		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	White blood cell count decreased	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.954
Investigations	White blood cell count decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	White blood cell count decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood urea increased		0%	2.2% (0.6, 8.4)	P=1.000, I <sup>2</sup> =0%	P=0.091, I <sup>2</sup> =0%							P=0.542
Investigations	Blood urea increased	Mild	0%	2.2% (0.6, 8.4)	P=1.000, I <sup>2</sup> =0%	P=0.091, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.022 (-0.052 - 0.008)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.542
Investigations	Blood urea increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Investigation s	Blood urea increased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Investigation s	Electrocardi ogram T wave peaked		1.2% (0.3, 4.5)	0%	P=0.096 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.629
Investigation s	Electrocardi ogram T wave peaked	Mild	1.2% (0.3, 4.5)	0%	P=0.096 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.011 (-0.004 - 0.027)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.629
Investigation s	Electrocardi ogram T wave peaked	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Investigation s	Electrocardi ogram T wave peaked	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Tri-iodothyronine free increased		0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.240, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.944
Investigations	Tri-iodothyronine free increased	Mild	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.240, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	0.512 (0.031, 8.376)	0.517 (0.033, 8.078)	-0.005 (-0.029, 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.944
Investigations	Tri-iodothyronine free increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Tri-iodothyronine free increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Blood iron decreased		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.681
Investigations	Blood iron decreased	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.681
Investigations	Blood iron decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood iron decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Thyroxine decreased		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.681
Investigations	Thyroxine decreased	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.681
Investigations	Thyroxine decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Thyroxine decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Transaminases increased		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Transaminases increased	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Investigations	Transaminases increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Transaminases increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood cortisol decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Blood cortisol decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686
Investigations	Blood cortisol decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood cortisol decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Cortisol free urine decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686
Investigations	Cortisol free urine decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Investigation s	Cortisol free urine decreased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Investigation s	Cortisol free urine decreased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Investigation s	Basophil count increased		0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.771
Investigation s	Basophil count increased	Mild	0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Investigation s	Basophil count increased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Investigation s	Basophil count increased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Investigation s	Blood cholesterol increased		0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.771
Investigation s	Blood cholesterol increased	Mild	0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Blood cholesterol increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood cholesterol increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood lactate dehydrogenase increased		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.678
Investigations	Blood lactate dehydrogenase increased	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Blood lactate dehydrogenase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood lactate dehydrogenase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood potassium increased		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.678
Investigations	Blood potassium increased	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Blood potassium increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood potassium increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood pressure increased		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.678
Investigations	Blood pressure increased	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Blood pressure increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Blood pressure increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Electrocardiogram ST segment abnormal		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.678
Investigations	Electrocardiogram ST segment abnormal	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678
Investigations	Electrocardiogram ST segment abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Electrocardiogram ST segment abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Electrocardiogram high voltage		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771
Investigations	Electrocardiogram high voltage	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Investigations	Electrocardiogram high voltage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Electrocardiogram high voltage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Haemoglobin decreased		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.678
Investigations	Haemoglobin decreased	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678
Investigations	Haemoglobin decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Haemoglobin decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Hepatic enzyme abnormal		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.678
Investigations	Hepatic enzyme abnormal	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678
Investigations	Hepatic enzyme abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Hepatic enzyme abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Hepatic enzyme increased		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.678
Investigations	Hepatic enzyme increased	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678
Investigations	Hepatic enzyme increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Hepatic enzyme increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Lipids increased		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.678
Investigations	Lipids increased	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678
Investigations	Lipids increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Lipids increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Thyroid function test abnormal		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.678
Investigations	Thyroid function test abnormal	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678
Investigations	Thyroid function test abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Thyroid function test abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Thyroxine free decreased		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771
Investigations	Thyroxine free decreased	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Investigations	Thyroxine free decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Investigations	Thyroxine free decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Liver function test abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.773
Investigations	Liver function test abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.773
Investigations	Liver function test abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Investigations	Liver function test abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Respiratory, thoracic and mediastinal disorders			29.5% (23.2, 36.7)	22.0% (14.6, 31.6)	P=0.263, I <sup>2</sup> =19.7%	P=0.113, I <sup>2</sup> =59%							P=0.263
Respiratory, thoracic and mediastinal disorders		Mild	25.4% (19.5, 32.4)	17.6% (11.1, 26.8)	P=0.016, I <sup>2</sup> =82.1%	P=0.086, I <sup>2</sup> =64%	1.612 (0.842, 3.087)	1.438 (0.868, 2.383) 0.158	0.077 (-0.023 - 0.177)	P=0.869, I <sup>2</sup> =0%	P=0.774, I <sup>2</sup> =0%	P=0.814, I <sup>2</sup> =0%	P=0.313

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders		Moderate	4.0% (1.9, 8.2)	4.4% (1.7, 11.1)	P=0.001, I <sup>2</sup> =0%	P=0.982, I <sup>2</sup> =0%	0.928 (0.265, 3.250)	0.931 (0.281, 3.082) 0.906	-0.003 (-0.054, 0.048)	P=0.091, I <sup>2</sup> =6506%	P=0.093, I <sup>2</sup> =6455%	P=0.100, I <sup>2</sup> =6307%	P=0.720
Respiratory, thoracic and mediastinal disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Respiratory, thoracic and mediastinal disorders	Cough		17.3% (12.4, 23.7)	13.2% (7.6, 21.8)	P=0.001, I <sup>2</sup> =89.1%	P=0.197, I <sup>2</sup> =37%							P=0.229

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders	Cough	Mild	16.8% (11.9, 23.1)	9.9% (5.2, 17.9)	P=0.000, I <sup>2</sup> =90.3%	P=0.273, I <sup>2</sup> =12%	1.851 (0.827, 4.141)	1.681 (0.839, 3.367) 0.143	0.067 (-0.014, 0.149)	P=0.381, I <sup>2</sup> =0%	P=0.442, I <sup>2</sup> =0%	P=0.098, I <sup>2</sup> =6356%	P=0.336
Respiratory, thoracic and mediastinal disorders	Cough	Moderate	0.6% (0.1, 4.0)	3.3% (1.1, 9.7)	P=0.236, I <sup>2</sup> =0%	P=0.541, I <sup>2</sup> =0%	0.174 (0.018, 1.674)	0.177 (0.019, 1.660) 0.129	-0.027 (-0.066, 0.011)	P=0.390, I <sup>2</sup> =0%	P=0.390, I <sup>2</sup> =0%	P=0.348, I <sup>2</sup> =0%	P=0.624
Respiratory, thoracic and mediastinal disorders	Cough	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea		2.3% (0.9, 6.0)	6.6% (3.0, 13.9)	P=0.018, I <sup>2</sup> =0%	P=0.379, I <sup>2</sup> =0%							P=0.794
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Mild	2.3% (0.9, 6.0)	6.6% (3.0, 13.9)	P=0.018, I <sup>2</sup> =0%	P=0.379, I <sup>2</sup> =0%	0.325 (0.088, 1.205)	0.346 (0.101, 1.189) 0.092	-0.043 (-0.099, 0.012)	P=0.351, I <sup>2</sup> =0%	P=0.338, I <sup>2</sup> =0%	P=0.900, I <sup>2</sup> =0%	P=0.794
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic		2.3% (0.9, 6.0)	3.3% (1.1, 9.7)	P=0.306, I <sup>2</sup> =0%	P=0.541, I <sup>2</sup> =0%							P=0.736

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Mild	2.3% (0.9, 6.0)	3.3% (1.1, 9.7)	P=0.306, I <sup>2</sup> =0%	P=0.541, I <sup>2</sup> =0%	0.688 (0.150, 3.156)	0.696 (0.160, 3.035) 0.63	-0.010 (-0.053, 0.033)	P=0.827, I <sup>2</sup> =0%	P=0.823, I <sup>2</sup> =0%	P=0.997, I <sup>2</sup> =0%	P=0.736
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Respiratory, thoracic and mediastinal disorders	Asthma		2.3% (0.9, 6.0)	2.2% (0.6, 8.4)	P=0.991, I <sup>2</sup> =0%	P=0.987, I <sup>2</sup> =0%							P=0.726
Respiratory, thoracic and mediastinal disorders	Asthma	Mild	1.7% (0.6, 5.2)	1.1% (0.2, 7.4)	P=0.563, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	1.576 (0.161, 15.427)	1.563 (0.167, 14.665) 0.696	0.006 (-0.023, 0.035)	P=0.734, I <sup>2</sup> =0%	P=0.733, I <sup>2</sup> =0%	P=0.840, I <sup>2</sup> =0%	P=0.673
Respiratory, thoracic and mediastinal disorders	Asthma	Moderate	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	0.529 (0.032, 8.665)	0.535 (0.034, 8.355) 0.655	-0.005 (-0.029, 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.949

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Respiratory, thoracic and mediastinal disorders	Asthma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Respiratory, thoracic and mediastinal disorders	Respiratory disorder		1.2% (0.3, 4.5)	2.2% (0.6, 8.4)	P=0.093 , I <sup>2</sup> =0%	P=0.096 , I <sup>2</sup> =0%							P=0.618
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Mild	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%	0.529 (0.032, 8.665)	0.535 (0.034, 8.355) 0.655	-0.005 (-0.029 - 0.019)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.652



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Moderate	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	0.529 (0.032, 8.665)	0.535 (0.034, 8.355) 0.655	-0.005 (-0.029 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.949
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Respiratory, thoracic and mediastinal disorders	Epistaxis		1.7% (0.6, 5.2)	0%	P=0.039, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.292

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders	Epistaxis	Mild	1.2% (0.3, 4.5)	0%	P=0.093, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.012 (-0.004 - 0.028)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.363
Respiratory, thoracic and mediastinal disorders	Epistaxis	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders	Epistaxis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Respiratory, thoracic and mediastinal disorders	Nasal congestion		1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.093, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.591
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Mild	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	0.529 (0.033, 8.356)	0.529 (0.034, 8.260) 0.65	-0.005 (-0.030, 0.019)	P=0.330, I <sup>2</sup> =0%	P=0.331, I <sup>2</sup> =0%	P=0.327, I <sup>2</sup> =0%	P=0.737

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Respiratory, thoracic and mediastinal disorders	Sinus congestion		1.7% (0.6, 5.2)	0%	P=0.039, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.536

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Mild	1.2% (0.3, 4.5)	0%	P=0.093, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.012 (-0.004 - 0.028)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.626
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders	Wheezing		1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.093, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.820
Respiratory, thoracic and mediastinal disorders	Wheezing	Mild	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	0.529 (0.032, 8.665)	0.535 (0.034, 8.355)	-0.005 (-0.029, 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.949
Respiratory, thoracic and mediastinal disorders	Wheezing	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.006 (-0.006, 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders	Wheezing	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Respiratory, thoracic and mediastinal disorders	Allergic cough		1.2% (0.3, 4.5)	0%	P=0.993, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.584

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders	Allergic cough	Mild	1.2% (0.3, 4.5)	0%	P=0.993, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.012 (-0.004 - 0.027)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.721, I <sup>2</sup> =0%	P=0.584
Respiratory, thoracic and mediastinal disorders	Allergic cough	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Respiratory, thoracic and mediastinal disorders	Allergic cough	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome		1.2% (0.3, 4.5)	0%	P=0.993, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.584
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Respiratory, thoracic and mediastinal disorders	Laryngospasm		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Respiratory, thoracic and mediastinal disorders	Nasal obstruction		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Respiratory, thoracic and mediastinal disorders	Productive cough		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771
Respiratory, thoracic and mediastinal disorders	Productive cough	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Respiratory, thoracic and mediastinal disorders	Productive cough	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Respiratory, thoracic and mediastinal disorders	Productive cough	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Gastrointestinal disorders			19.1% (13.9, 25.6)	18.7% (11.9, 28.0)	P=0.314, I <sup>2</sup> =0.2%	P=0.161, I <sup>2</sup> =47%							P=0.551
Gastrointestinal disorders		Mild	18.5% (13.4, 25.0)	17.6% (11.1, 26.8)	P=0.412, I <sup>2</sup> =0%	P=0.086, I <sup>2</sup> =64%	1.062 (0.550, 2.051)	1.051 (0.609, 1.814) 0.858	0.009 (-0.089, 0.107)	P=0.066, I <sup>2</sup> =7049%	P=0.067, I <sup>2</sup> =7017%	P=0.058, I <sup>2</sup> =7219%	P=0.342
Gastrointestinal disorders		Moderate	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	0.529 (0.032, 8.665)	0.535 (0.034, 8.355) 0.655	-0.005 (-0.029, 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.738

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Gastrointestinal disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Gastrointestinal disorders	Diarrhoea		5.2% (2.7, 9.7)	7.7% (3.7, 15.3)	P=0.745, I <sup>2</sup> =0%	P=0.219, I <sup>2</sup> =27%							P=0.521
Gastrointestinal disorders	Diarrhoea	Mild	5.2% (2.7, 9.7)	7.7% (3.7, 15.3)	P=0.745, I <sup>2</sup> =0%	P=0.219, I <sup>2</sup> =27%	0.655 (0.236, 1.822)	0.674 (0.260, 1.745) 0.416	-0.025 (-0.089, 0.039)	P=0.475, I <sup>2</sup> =0%	P=0.484, I <sup>2</sup> =0%	P=0.357, I <sup>2</sup> =0%	P=0.521
Gastrointestinal disorders	Diarrhoea	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Gastrointestinal disorders	Diarrhoea	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Gastrointestinal disorders	Vomiting		5.8% (3.1, 10.4)	1.1% (0.2, 7.4)	P=0.005, I <sup>2</sup> =78.7%	P=0.241, I <sup>2</sup> =0%							P=0.058
Gastrointestinal disorders	Vomiting	Mild	5.8% (3.1, 10.4)	1.1% (0.2, 7.4)	P=0.005, I <sup>2</sup> =78.7%	P=0.241, I <sup>2</sup> =0%	5.844 (0.723, 47.258)	5.337 (0.702, 40.581) 0.106	0.047 (0.007 - 0.088)	P=0.422, I <sup>2</sup> =0%	P=0.447, I <sup>2</sup> =0%	P=0.028, I <sup>2</sup> =7924%	P=0.106
Gastrointestinal disorders	Vomiting	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.763

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Gastrointesti nal disorders	Vomiting	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Gastrointesti nal disorders	Nausea		2.9% (1.2, 6.8)	1.1% (0.2, 7.4)	P=0.156 , I <sup>2</sup> =38%	P=0.241 , I <sup>2</sup> =0%							P=0.225
Gastrointesti nal disorders	Nausea	Mild	2.3% (0.9, 6.0)	0%	P=0.296 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.023 (0.001 - 0.046)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.38 7, I <sup>2</sup> =0%	P=0.200
Gastrointesti nal disorders	Nausea	Moderate	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%	0.529 (0.032, 8.665)	0.535 (0.034, 8.355) 0.655	-0.005 (-0.029 - 0.019)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.949

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Gastrointesti nal disorders	Nausea	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Gastrointesti nal disorders	Abdominal pain		1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.093 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%							P=0.972
Gastrointesti nal disorders	Abdominal pain	Mild	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%	0.529 (0.032, 8.665)	0.535 (0.034, 8.355)	-0.005 (-0.029 - 0.019)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.717
Gastrointesti nal disorders	Abdominal pain	Moderate	0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.769



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Gastrointesti nal disorders	Abdominal pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Gastrointesti nal disorders	Abdominal pain upper		2.3% (0.9, 6.0)	0%	P=0.991 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.319
Gastrointesti nal disorders	Abdominal pain upper	Mild	2.3% (0.9, 6.0)	0%	P=0.991 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.023 (0.001 - 0.046)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.74 8, I <sup>2</sup> =0%	P=0.319
Gastrointesti nal disorders	Abdominal pain upper	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Gastrointesti nal disorders	Abdominal pain upper	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Gastrointestinal disorders	Dyspepsia		2.3% (0.9, 6.0)	2.2% (0.6, 8.4)	P=0.991, I <sup>2</sup> =0%	P=0.091, I <sup>2</sup> =0%							P=0.834
Gastrointestinal disorders	Dyspepsia	Mild	2.3% (0.9, 6.0)	2.2% (0.6, 8.4)	P=0.991, I <sup>2</sup> =0%	P=0.091, I <sup>2</sup> =0%	1.047 (0.189, 5.810)	1.046 (0.197, 5.567) 0.958	0.001 (-0.037, 0.039)	P=0.344, I <sup>2</sup> =0%	P=0.345, I <sup>2</sup> =0%	P=0.328, I <sup>2</sup> =0%	P=0.834
Gastrointestinal disorders	Dyspepsia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Gastrointestinal disorders	Dyspepsia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Gastrointesti nal disorders	Constipation		1.7% (0.6, 5.2)	1.1% (0.2, 7.4)	P=0.039 , I <sup>2</sup> =0%	P=0.233 , I <sup>2</sup> =0%							P=0.808
Gastrointesti nal disorders	Constipation	Mild	1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.093 , I <sup>2</sup> =0%	P=0.233 , I <sup>2</sup> =0%	1.057 (0.097, 11.555)	1.057 (0.098, 11.454)	0.001 (-0.026 - 0.028)	P=0.204, I <sup>2</sup> =3815%	P=0.205, I <sup>2</sup> =3774%	P=0.210, I <sup>2</sup> =3641%	P=0.904
Gastrointesti nal disorders	Constipation	Moderate	0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Gastrointesti nal disorders	Constipation	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Gastrointestinal disorders	Toothache		0.6% (0.1, 4.0)	2.2% (0.6, 8.4)	P=0.236, I <sup>2</sup> =0%	P=0.987, I <sup>2</sup> =0%							P=0.434
Gastrointestinal disorders	Toothache	Mild	0.6% (0.1, 4.0)	2.2% (0.6, 8.4)	P=0.236, I <sup>2</sup> =0%	P=0.987, I <sup>2</sup> =0%	0.262 (0.023, 2.918)	0.266 (0.025, 2.862)	-0.016 (-0.048, 0.016)	P=0.575, I <sup>2</sup> =0%	P=0.574, I <sup>2</sup> =0%	P=0.642, I <sup>2</sup> =0%	P=0.434
Gastrointestinal disorders	Toothache	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Gastrointestinal disorders	Toothache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Gastrointestinal disorders	Abdominal discomfort		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.957
Gastrointestinal disorders	Abdominal discomfort	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.957
Gastrointestinal disorders	Abdominal discomfort	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Gastrointestinal disorders	Abdominal discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Gastrointestinal disorders	Enteritis		0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.240, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.944

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Gastrointestinal disorders	Enteritis	Mild	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.240, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	0.512 (0.031, 8.376)	0.517 (0.033, 8.078) 0.638	-0.005 (-0.029 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.944
Gastrointestinal disorders	Enteritis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Gastrointestinal disorders	Enteritis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Gastrointestinal disorders	Gastrointestinal disorder		1.2% (0.3, 4.5)	0%	P=0.096, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.629

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Gastrointestinal disorders	Gastrointestinal disorder	Mild	1.2% (0.3, 4.5)	0%	P=0.096, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.011 (-0.004 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.629
Gastrointestinal disorders	Gastrointestinal disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Gastrointestinal disorders	Gastrointestinal disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Gastrointestinal disorders	Aphthous ulcer		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.681

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Gastrointestinal disorders	Aphthous ulcer	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.681
Gastrointestinal disorders	Aphthous ulcer	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Gastrointestinal disorders	Aphthous ulcer	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Gastrointestinal disorders	Gastric disorder		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Gastrointesti nal disorders	Gastric disorder	Mild	0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.769
Gastrointesti nal disorders	Gastric disorder	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Gastrointesti nal disorders	Gastric disorder	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Gastrointesti nal disorders	Gastrointesti nal motility disorder		0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.769
Gastrointesti nal disorders	Gastrointesti nal motility disorder	Mild	0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Gastrointestinal disorders	Gastrointestinal motility disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Gastrointestinal disorders	Gastrointestinal motility disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Gastrointestinal disorders	Lip swelling		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686
Gastrointestinal disorders	Lip swelling	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Gastrointesti nal disorders	Lip swelling	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Gastrointesti nal disorders	Lip swelling	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Gastrointesti nal disorders	Abdominal distension		0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.771
Gastrointesti nal disorders	Abdominal distension	Mild	0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.771
Gastrointesti nal disorders	Abdominal distension	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Gastrointestinal disorders	Abdominal distension	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Gastrointestinal disorders	Noninfective gingivitis		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.678
Gastrointestinal disorders	Noninfective gingivitis	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678
Gastrointestinal disorders	Noninfective gingivitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Gastrointestinal disorders	Noninfective gingivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
General disorders and administration site conditions			19.7% (14.4, 26.2)	18.7% (11.9, 28.0)	P=0.466, I <sup>2</sup> =0%	P=0.161, I <sup>2</sup> =47%							P=0.213
General disorders and administration site conditions		Mild	16.2% (11.4, 22.4)	15.4% (9.3, 24.3)	P=0.227, I <sup>2</sup> =30.3%	P=0.070, I <sup>2</sup> =67%	1.057 (0.523, 2.138)	1.047 (0.584, 1.877) 0.878	0.007 (-0.084, 0.099)	P=0.435, I <sup>2</sup> =0%	P=0.431, I <sup>2</sup> =0%	P=0.446, I <sup>2</sup> =0%	P=0.228

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions		Moderate	3.5% (1.6, 7.5)	3.3% (1.1, 9.7)	P=0.394, I <sup>2</sup> =0%	P=0.566, I <sup>2</sup> =0%	1.060 (0.258, 4.353)	1.058 (0.272, 4.121) 0.935	0.002 (-0.044 - 0.048)	P=0.981, I <sup>2</sup> =0%	P=0.982, I <sup>2</sup> =0%	P=0.959, I <sup>2</sup> =0%	P=0.710
General disorders and administration site conditions		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Pyrexia		16.2% (11.4, 22.4)	12.1% (6.8, 20.5)	P=0.704, I <sup>2</sup> =0%	P=0.094, I <sup>2</sup> =60%							P=0.736
General disorders and administration site conditions	Pyrexia	Mild	13.3% (9.0, 19.2)	11.0% (6.0, 19.2)	P=0.274, I <sup>2</sup> =14.7%	P=0.163, I <sup>2</sup> =44%	1.239 (0.559, 2.742)	1.204 (0.602, 2.408) 0.599	0.022 (-0.059, 0.104)	P=0.579, I <sup>2</sup> =0%	P=0.567, I <sup>2</sup> =0%	P=0.668, I <sup>2</sup> =0%	P=0.794

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Pyrexia	Moderate	2.9% (1.2, 6.8)	1.1% (0.2, 7.4)	P=0.156, I <sup>2</sup> =38%	P=0.233, I <sup>2</sup> =0%	2.651 (0.311, 22.579)	2.632 (0.313, 22.142) 0.373	0.018 (-0.015 - 0.051)	P=0.218, I <sup>2</sup> =3408%	P=0.218, I <sup>2</sup> =3414%	P=0.155, I <sup>2</sup> =5058%	P=0.592
General disorders and administration site conditions	Pyrexia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
General disorders and administration site conditions	Injection site pain		1.7% (0.6, 5.2)	0%	P=0.041, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.540



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Injection site pain	Mild	1.7% (0.6, 5.2)	0%	P=0.041, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.017 (-0.002 - 0.037)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.540
General disorders and administration site conditions	Injection site pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Injection site pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
General disorders and administration site conditions	Injection site pruritus		1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.096, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.827

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Injection site pruritus	Mild	1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.096, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	1.035 (0.091, 11.735)	1.034 (0.096, 11.103) 0.978	0.000 (-0.026 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.827
General disorders and administration site conditions	Injection site pruritus	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
General disorders and administration site conditions	Injection site pruritus	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
General disorders and administrati on site conditions	Fatigue		0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%							P=0.949
General disorders and administrati on site conditions	Fatigue	Mild	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%	0.529 (0.032, 8.665)	0.535 (0.034, 8.355) 0.655	-0.005 (-0.029 - 0.019)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.949

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Fatigue	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
General disorders and administration site conditions	Fatigue	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
General disorders and administrati on site conditions	Injection site swelling		0%	1.1% (0.2, 7.4)	P=1.000 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%							P=0.947
General disorders and administrati on site conditions	Injection site swelling	Mild	0%	1.1% (0.2, 7.4)	P=1.000 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.947
General disorders and administrati on site conditions	Injection site swelling	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Injection site swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
General disorders and administration site conditions	Injection site erythema		0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.240, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.944

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Injection site erythema	Mild	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.240, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	0.512 (0.031, 8.376)	0.517 (0.033, 8.078) 0.638	-0.005 (-0.029 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.944
General disorders and administration site conditions	Injection site erythema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
General disorders and administrati on site conditions	Injection site erythema	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
General disorders and administrati on site conditions	Injection site reaction		1.2% (0.3, 4.5)	0%	P=0.096 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.629
General disorders and administrati on site conditions	Injection site reaction	Mild	0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Injection site reaction	Moderate	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
General disorders and administration site conditions	Injection site reaction	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Face oedema		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.681
General disorders and administration site conditions	Face oedema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Face oedema	Moderate	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.681
General disorders and administration site conditions	Face oedema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
General disorders and administration site conditions	Gait disturbance		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
General disorders and administrati on site conditions	Gait disturbance	Mild	0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.769
General disorders and administrati on site conditions	Gait disturbance	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Gait disturbance	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
General disorders and administration site conditions	Influenza like illness		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.681

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Influenza like illness	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
General disorders and administration site conditions	Influenza like illness	Moderate	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.681
General disorders and administration site conditions	Influenza like illness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
General disorders and administrati on site conditions	Injection site atrophy		0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.769
General disorders and administrati on site conditions	Injection site atrophy	Mild	0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.769



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
General disorders and administrati on site conditions	Injection site atrophy	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
General disorders and administrati on site conditions	Injection site atrophy	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
General disorders and administrati on site conditions	Injection site urticaria		0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.769
General disorders and administrati on site conditions	Injection site urticaria	Mild	0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.769
General disorders and administrati on site conditions	Injection site urticaria	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Injection site urticaria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
General disorders and administration site conditions	Medical device discomfort		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.763

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Medical device discomfort	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.763
General disorders and administration site conditions	Medical device discomfort	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Medical device discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
General disorders and administration site conditions	Vaccination site pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.763
General disorders and administration site conditions	Vaccination site pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.763

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
General disorders and administrati on site conditions	Vaccination site pain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
General disorders and administrati on site conditions	Vaccination site pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
General disorders and administrati on site conditions	Injection site bruising		0%	1.1% (0.2, 7.4)	P=1.000 , I <sup>2</sup> =0%	P=0.233 , I <sup>2</sup> =0%							P=0.678
General disorders and administrati on site conditions	Injection site bruising	Mild	0%	1.1% (0.2, 7.4)	P=1.000 , I <sup>2</sup> =0%	P=0.233 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.678

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Injection site bruising	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
General disorders and administration site conditions	Injection site bruising	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
General disorders and administration site conditions	Injection site haemorrhage		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.678



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Injection site haemorrhage	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678
General disorders and administration site conditions	Injection site haemorrhage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Injection site haemorrhage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
General disorders and administration site conditions	Peripheral swelling		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Peripheral swelling	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
General disorders and administration site conditions	Peripheral swelling	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
General disorders and administration site conditions	Peripheral swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.773
General disorders and administration site conditions	Pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.773

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
General disorders and administration site conditions	Pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
General disorders and administration site conditions	Pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Nervous system disorders			8.1% (4.9, 13.2)	11.0% (6.0, 19.2)	P=0.000, I <sup>2</sup> =85.2%	P=0.186, I <sup>2</sup> =38%							P=0.158

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Nervous system disorders		Mild	5.8% (3.1, 10.4)	7.7% (3.7, 15.3)	P=0.005, I <sup>2</sup> =78.7%	P=0.716, I <sup>2</sup> =0%	0.742 (0.271, 2.028)	0.759 (0.301, 1.915) 0.559	-0.019 (-0.083, 0.046)	P=0.128, I <sup>2</sup> =5685%	P=0.126, I <sup>2</sup> =5724%	P=0.245, I <sup>2</sup> =2608%	P=0.177
Nervous system disorders		Moderate	2.3% (0.9, 6.0)	3.3% (1.1, 9.7)	P=0.017, I <sup>2</sup> =0%	P=0.041, I <sup>2</sup> =0%	0.699 (0.150, 3.267)	0.713 (0.167, 3.051) 0.649	-0.009 (-0.052, 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.926
Nervous system disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Nervous system disorders	Headache		6.9% (4.0, 11.8)	9.9% (5.2, 17.9)	P=0.000, I <sup>2</sup> =0%	P=0.304, I <sup>2</sup> =0%							P=0.309

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Nervous system disorders	Headache	Mild	4.6% (2.3, 9.0)	6.6% (3.0, 13.9)	P=0.001, I <sup>2</sup> =0%	P=0.978, I <sup>2</sup> =0%	0.695 (0.233, 2.069)	0.709 (0.255, 1.973) 0.51	-0.019 (-0.079, 0.041)	P=0.064, I <sup>2</sup> =7079%	P=0.065, I <sup>2</sup> =7058%	P=0.107, I <sup>2</sup> =6161%	P=0.317
Nervous system disorders	Headache	Moderate	2.3% (0.9, 6.0)	3.3% (1.1, 9.7)	P=0.017, I <sup>2</sup> =0%	P=0.041, I <sup>2</sup> =0%	0.699 (0.150, 3.267)	0.713 (0.167, 3.051) 0.649	-0.009 (-0.052, 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.926
Nervous system disorders	Headache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Nervous system disorders	Dizziness		1.7% (0.6, 5.2)	0%	P=0.550, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.255

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Nervous system disorders	Dizziness	Mild	1.7% (0.6, 5.2)	0%	P=0.550, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.017 (-0.002 - 0.037)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.585, I <sup>2</sup> =0%	P=0.255
Nervous system disorders	Dizziness	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Nervous system disorders	Dizziness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Nervous system disorders	Post-traumatic headache		0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.949



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Nervous system disorders	Post-traumatic headache	Mild	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	0.529 (0.032, 8.665)	0.535 (0.034, 8.355) 0.655	-0.005 (-0.029, 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.949
Nervous system disorders	Post-traumatic headache	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Nervous system disorders	Post-traumatic headache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Nervous system disorders	Migraine		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.681

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Nervous system disorders	Migraine	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.681
Nervous system disorders	Migraine	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Nervous system disorders	Migraine	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Nervous system disorders	Tremor		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769
Nervous system disorders	Tremor	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Nervous system disorders	Tremor	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Nervous system disorders	Tremor	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications			9.8% (6.2, 15.2)	7.7% (3.7, 15.3)	P=0.190, I <sup>2</sup> =39.3%	P=0.243, I <sup>2</sup> =20%							P=0.999

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Injury, poisoning and procedural complications		Mild	6.9% (4.0, 11.8)	6.6% (3.0, 13.9)	P=0.535, I <sup>2</sup> =0%	P=0.409, I <sup>2</sup> =0%	1.060 (0.384, 2.932)	1.056 (0.410, 2.718) 0.91	0.004 (-0.060 - 0.067)	P=0.751, I <sup>2</sup> =0%	P=0.749, I <sup>2</sup> =0%	P=0.766, I <sup>2</sup> =0%	P=0.911
Injury, poisoning and procedural complications		Moderate	2.9% (1.2, 6.8)	1.1% (0.2, 7.4)	P=0.156, I <sup>2</sup> =38%	P=0.241, I <sup>2</sup> =0%	2.744 (0.312, 24.170)	2.663 (0.318, 22.312) 0.367	0.018 (-0.015 - 0.051)	P=0.697, I <sup>2</sup> =0%	P=0.703, I <sup>2</sup> =0%	P=0.536, I <sup>2</sup> =0%	P=0.726
Injury, poisoning and procedural complications		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Injury, poisoning and procedural complications	Head injury		1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.993 , I <sup>2</sup> =0%	P=0.233 , I <sup>2</sup> =0%							P=0.842
Injury, poisoning and procedural complications	Head injury	Mild	1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.993 , I <sup>2</sup> =0%	P=0.233 , I <sup>2</sup> =0%	1.047 (0.094, 11.646)	1.046 (0.097, 11.279) 0.97	0.001 (-0.026 - 0.027)	P=0.569, I <sup>2</sup> =0%	P=0.569, I <sup>2</sup> =0%	P=0.587, I <sup>2</sup> =0%	P=0.842
Injury, poisoning and procedural complications	Head injury	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Injury, poisoning and procedural complications	Head injury	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Animal bite		0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%							P=0.949
Injury, poisoning and procedural complications	Animal bite	Mild	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%	0.529 (0.032, 8.665)	0.535 (0.034, 8.355) 0.655	-0.005 (-0.029 - 0.019)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.949

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Injury, poisoning and procedural complications	Animal bite	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Animal bite	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Injury, poisoning and procedural complications	Arthropod bite		0%	1.1% (0.2, 7.4)	P=1.000 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%							P=0.422
Injury, poisoning and procedural complications	Arthropod bite	Mild	0%	1.1% (0.2, 7.4)	P=1.000 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.422
Injury, poisoning and procedural complications	Arthropod bite	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Injury, poisoning and procedural complications	Arthropod bite	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Contusion		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.957
Injury, poisoning and procedural complications	Contusion	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Injury, poisoning and procedural complications	Contusion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686
Injury, poisoning and procedural complications	Contusion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Ligament sprain		1.2% (0.3, 4.5)	0%	P=0.993, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.584

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Injury, poisoning and procedural complications	Ligament sprain	Mild	1.2% (0.3, 4.5)	0%	P=0.993, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.012 (-0.004 - 0.027)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.721, I <sup>2</sup> =0%	P=0.584
Injury, poisoning and procedural complications	Ligament sprain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Ligament sprain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Injury, poisoning and procedural complications	Post-traumatic pain		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.486
Injury, poisoning and procedural complications	Post-traumatic pain	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.486

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Injury, poisoning and procedural complications	Post-traumatic pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Post-traumatic pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Skin laceration		1.2% (0.3, 4.5)	0%	P=0.096, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.629

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Injury, poisoning and procedural complications	Skin laceration	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Injury, poisoning and procedural complications	Skin laceration	Moderate	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Injury, poisoning and procedural complications	Skin laceration	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Injury, poisoning and procedural complications	Ankle fracture		0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.769
Injury, poisoning and procedural complications	Ankle fracture	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Ankle fracture	Moderate	0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Injury, poisoning and procedural complications	Ankle fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Burns first degree		0%	1.1% (0.2, 7.4)	P=1.000 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%							P=0.681
Injury, poisoning and procedural complications	Burns first degree	Mild	0%	1.1% (0.2, 7.4)	P=1.000 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.681



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Injury, poisoning and procedural complications	Burns first degree	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Burns first degree	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Injury, poisoning and procedural complications	Burns second degree		0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.769
Injury, poisoning and procedural complications	Burns second degree	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Burns second degree	Moderate	0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Injury, poisoning and procedural complications	Burns second degree	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Concussion		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.681
Injury, poisoning and procedural complications	Concussion	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.681

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Injury, poisoning and procedural complications	Concussion	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Concussion	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Face injury		0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Injury, poisoning and procedural complications	Face injury	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Face injury	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Injury, poisoning and procedural complications	Face injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Injury, poisoning and procedural complications	Fall		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769
Injury, poisoning and procedural complications	Fall	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Injury, poisoning and procedural complications	Fall	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Fall	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Laceration		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Injury, poisoning and procedural complications	Laceration	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Injury, poisoning and procedural complications	Laceration	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Laceration	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Injury, poisoning and procedural complications	Meniscus injury		0%	1.1% (0.2, 7.4)	P=1.000 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%							P=0.681
Injury, poisoning and procedural complications	Meniscus injury	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Meniscus injury	Moderate	0%	1.1% (0.2, 7.4)	P=1.000 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.681

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Injury, poisoning and procedural complications	Meniscus injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Muscle strain		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769
Injury, poisoning and procedural complications	Muscle strain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Injury, poisoning and procedural complications	Muscle strain	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Injury, poisoning and procedural complications	Muscle strain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Injury, poisoning and procedural complications	Radius fracture		0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.769
Injury, poisoning and procedural complications	Radius fracture	Mild	0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Injury, poisoning and procedural complications	Radius fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Injury, poisoning and procedural complications	Radius fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Wrist fracture		0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.769
Injury, poisoning and procedural complications	Wrist fracture	Mild	0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Injury, poisoning and procedural complications	Wrist fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Wrist fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Thermal burn		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.763

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Injury, poisoning and procedural complications	Thermal burn	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.763
Injury, poisoning and procedural complications	Thermal burn	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Thermal burn	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Injury, poisoning and procedural complications	Upper limb fracture		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686
Injury, poisoning and procedural complications	Upper limb fracture	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Injury, poisoning and procedural complications	Upper limb fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Upper limb fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Animal scratch		0%	1.1% (0.2, 7.4)	P=1.000 , I <sup>2</sup> =0%	P=0.233 , I <sup>2</sup> =0%							P=0.678

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Injury, poisoning and procedural complications	Animal scratch	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678
Injury, poisoning and procedural complications	Animal scratch	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Animal scratch	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Injury, poisoning and procedural complications	Eye injury		0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.771
Injury, poisoning and procedural complications	Eye injury	Mild	0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.771
Injury, poisoning and procedural complications	Eye injury	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Injury, poisoning and procedural complications	Eye injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Joint injury		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771
Injury, poisoning and procedural complications	Joint injury	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Injury, poisoning and procedural complications	Joint injury	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Injury, poisoning and procedural complications	Joint injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders			7.5% (4.4, 12.5)	6.6% (3.0, 13.9)	P=0.790, I <sup>2</sup> =0%	P=0.409, I <sup>2</sup> =0%							P=0.242

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Skin and subcutaneous tissue disorders		Mild	6.9% (4.0, 11.8)	4.4% (1.7, 11.1)	P=0.563, I <sup>2</sup> =0%	P=0.982, I <sup>2</sup> =0%	1.618 (0.506, 5.169)	1.575 (0.523, 4.748) 0.42	0.025 (-0.031, 0.082)	P=0.784, I <sup>2</sup> =0%	P=0.788, I <sup>2</sup> =0%	P=0.711, I <sup>2</sup> =0%	P=0.405
Skin and subcutaneous tissue disorders		Moderate	0.6% (0.1, 4.0)	2.2% (0.6, 8.4)	P=0.236, I <sup>2</sup> =0%	P=0.096, I <sup>2</sup> =0%	0.259 (0.023, 2.934)	0.267 (0.025, 2.871) 0.276	-0.016 (-0.048, 0.016)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.721
Skin and subcutaneous tissue disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Skin and subcutaneous tissue disorders	Rash		1.7% (0.6, 5.2)	2.2% (0.6, 8.4)	P=0.039, I <sup>2</sup> =0%	P=0.987, I <sup>2</sup> =0%							P=0.877
Skin and subcutaneous tissue disorders	Rash	Mild	1.7% (0.6, 5.2)	2.2% (0.6, 8.4)	P=0.039, I <sup>2</sup> =0%	P=0.987, I <sup>2</sup> =0%	0.794 (0.131, 4.828)	0.798 (0.137, 4.656) 0.802	-0.004 (-0.040 - 0.031)	P=0.262, I <sup>2</sup> =2056%	P=0.263, I <sup>2</sup> =2029%	P=0.309, I <sup>2</sup> =350%	P=0.877
Skin and subcutaneous tissue disorders	Rash	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders	Rash	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Skin and subcutaneous tissue disorders	Urticaria		1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.993, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.665
Skin and subcutaneous tissue disorders	Urticaria	Mild	1.2% (0.3, 4.5)	0%	P=0.993, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.012 (-0.004 - 0.027)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.721, I <sup>2</sup> =0%	P=0.972
Skin and subcutaneous tissue disorders	Urticaria	Moderate	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.011 (-0.032 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.681



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Skin and subcutaneous tissue disorders	Urticaria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders	Dermatitis allergic		1.2% (0.3, 4.5)	2.2% (0.6, 8.4)	P=0.096, I <sup>2</sup> =0%	P=0.987, I <sup>2</sup> =0%							P=0.966
Skin and subcutaneous tissue disorders	Dermatitis allergic	Mild	1.2% (0.3, 4.5)	2.2% (0.6, 8.4)	P=0.096, I <sup>2</sup> =0%	P=0.987, I <sup>2</sup> =0%	0.515 (0.071, 3.741)	0.520 (0.074, 3.662)	-0.011 (-0.045, 0.023)	P=0.387, I <sup>2</sup> =0%	P=0.387, I <sup>2</sup> =0%	P=0.475, I <sup>2</sup> =0%	P=0.966
Skin and subcutaneous tissue disorders	Dermatitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Skin and subcutaneous tissue disorders	Dermatitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders	Eczema		1.2% (0.3, 4.5)	0%	P=0.993, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.858
Skin and subcutaneous tissue disorders	Eczema	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.936

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Skin and subcutaneous tissue disorders	Eczema	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Skin and subcutaneous tissue disorders	Eczema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders	Dermatitis contact		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.501
Skin and subcutaneous tissue disorders	Dermatitis contact	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.501

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Skin and subcutaneous tissue disorders	Dermatitis contact	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders	Dermatitis contact	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders	Urticaria papular		1.2% (0.3, 4.5)	0%	P=0.096, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.629

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Skin and subcutaneous tissue disorders	Urticaria papular	Mild	1.2% (0.3, 4.5)	0%	P=0.096, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.011 (-0.004 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.629
Skin and subcutaneous tissue disorders	Urticaria papular	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders	Urticaria papular	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders	Rash erythematous		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Skin and subcutaneous tissue disorders	Rash erythematous	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Skin and subcutaneous tissue disorders	Rash erythematous	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders	Rash erythematous	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Skin and subcutaneous tissue disorders	Rash pruritic		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.681
Skin and subcutaneous tissue disorders	Rash pruritic	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders	Rash pruritic	Moderate	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.011 (-0.032 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.681
Skin and subcutaneous tissue disorders	Rash pruritic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Skin and subcutaneous tissue disorders	Cafe au lait spots		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686
Skin and subcutaneous tissue disorders	Cafe au lait spots	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686
Skin and subcutaneous tissue disorders	Cafe au lait spots	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Skin and subcutaneous tissue disorders	Cafe au lait spots	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders	Keratosis pilaris		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686
Skin and subcutaneous tissue disorders	Keratosis pilaris	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686
Skin and subcutaneous tissue disorders	Keratosis pilaris	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Skin and subcutaneous tissue disorders	Keratosis pilaris	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders	Petechiae		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686
Skin and subcutaneous tissue disorders	Petechiae	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Skin and subcutaneous tissue disorders	Petechiae	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders	Petechiae	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders	Pityriasis alba		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686
Skin and subcutaneous tissue disorders	Pityriasis alba	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Skin and subcutaneous tissue disorders	Pityriasis alba	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders	Pityriasis alba	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders	Dyshidrotic eczema		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders	Urticaria chronic		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Skin and subcutaneous tissue disorders	Urticaria chronic	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Skin and subcutaneous tissue disorders	Urticaria chronic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders	Urticaria chronic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Skin and subcutaneous tissue disorders	Dermatitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.670
Skin and subcutaneous tissue disorders	Dermatitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.670
Skin and subcutaneous tissue disorders	Dermatitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Skin and subcutaneous tissue disorders	Dermatitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Eye disorders			8.7% (5.3, 13.9)	5.5% (2.3, 12.5)	P=0.180 , I <sup>2</sup> =41.2 %	P=0.626 , I <sup>2</sup> =0%							P=0.425
Eye disorders		Mild	8.1% (4.9, 13.2)	5.5% (2.3, 12.5)	P=0.271 , I <sup>2</sup> =14.1 %	P=0.626 , I <sup>2</sup> =0%	1.510 (0.525, 4.343)	1.467 (0.546, 3.937) 0.447	0.026 (-0.036 - 0.088)	P=0.875, I <sup>2</sup> =0%	P=0.886, I <sup>2</sup> =0%	P=0.719, I <sup>2</sup> =0%	P=0.458
Eye disorders		Moderate	0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Eye disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Eye disorders	Refraction disorder		1.7% (0.6, 5.2)	2.2% (0.6, 8.4)	P=0.041, I <sup>2</sup> =0%	P=0.091, I <sup>2</sup> =0%							P=0.899
Eye disorders	Refraction disorder	Mild	1.7% (0.6, 5.2)	2.2% (0.6, 8.4)	P=0.041, I <sup>2</sup> =0%	P=0.091, I <sup>2</sup> =0%	0.768 (0.124, 4.770)	0.776 (0.134, 4.477)	-0.005 (-0.040, 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.899
Eye disorders	Refraction disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Eye disorders	Refraction disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Eye disorders	Strabismus		0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.949
Eye disorders	Strabismus	Mild	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	0.529 (0.032, 8.665)	0.535 (0.034, 8.355) 0.655	-0.005 (-0.029, 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.949
Eye disorders	Strabismus	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Eye disorders	Strabismus	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Eye disorders	Conjunctivit is allergic		1.2% (0.3, 4.5)	0%	P=0.993 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.584
Eye disorders	Conjunctivit is allergic	Mild	1.2% (0.3, 4.5)	0%	P=0.993 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.012 (-0.004 - 0.027)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.72 1, I <sup>2</sup> =0%	P=0.584
Eye disorders	Conjunctivit is allergic	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Eye disorders	Conjunctivit is allergic	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Eye disorders	Myopia		0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.240 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%							P=0.950

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Eye disorders	Myopia	Mild	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.240, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	0.523 (0.032, 8.464)	0.523 (0.032, 8.563) 0.65	-0.005 (-0.029 - 0.019)	P=0.344, I <sup>2</sup> =0%	P=0.346, I <sup>2</sup> =0%	P=0.339, I <sup>2</sup> =0%	P=0.950
Eye disorders	Myopia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Eye disorders	Myopia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Eye disorders	Eye swelling		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Eye disorders	Eye swelling	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.686
Eye disorders	Eye swelling	Moderate	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Eye disorders	Eye swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Eye disorders	Papilloedema		0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.240, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.944

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Eye disorders	Papilloedema	Mild	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.240, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	0.512 (0.031, 8.376)	0.517 (0.033, 8.078) 0.638	-0.005 (-0.029, 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.944
Eye disorders	Papilloedema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Eye disorders	Papilloedema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Eye disorders	Astigmatism		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Eye disorders	Astigmatism	Mild	0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.769
Eye disorders	Astigmatism	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Eye disorders	Astigmatism	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Eye disorders	Eye haemorrhage		0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.769
Eye disorders	Eye haemorrhage	Mild	0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Eye disorders	Eye haemorrhage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Eye disorders	Eye haemorrhage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Eye disorders	Hypermetropia		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769
Eye disorders	Hypermetropia	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Eye disorders	Hypermetropia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Eye disorders	Hypermetropia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Eye disorders	Corneal epithelium defect		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771
Eye disorders	Corneal epithelium defect	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Eye disorders	Corneal epithelium defect	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Eye disorders	Corneal epithelium defect	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Eye disorders	Eye pain		0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.771
Eye disorders	Eye pain	Mild	0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.771
Eye disorders	Eye pain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Eye disorders	Eye pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Eye disorders	Vitreous opacities		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771
Eye disorders	Vitreous opacities	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Eye disorders	Vitreous opacities	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Eye disorders	Vitreous opacities	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Eye disorders	Xerophthalmia		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.678
Eye disorders	Xerophthalmia	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678
Eye disorders	Xerophthalmia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Eye disorders	Xerophthalmia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Eye disorders	Vernal keratoconjunctivitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.773
Eye disorders	Vernal keratoconjunctivitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.773
Eye disorders	Vernal keratoconjunctivitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Eye disorders	Vernal keratoconjunctivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Musculoskeletal and connective tissue disorders			7.5% (4.4, 12.5)	5.5% (2.3, 12.5)	P=0.139, I <sup>2</sup> =50.8%	P=0.008, I <sup>2</sup> =0%							P=0.841
Musculoskeletal and connective tissue disorders		Mild	6.4% (3.6, 11.1)	5.5% (2.3, 12.5)	P=0.337, I <sup>2</sup> =0%	P=0.008, I <sup>2</sup> =0%	1.182 (0.393, 3.554)	1.167 (0.421, 3.239) 0.766	0.009 (-0.050, 0.068)	P=0.217, I <sup>2</sup> =3425%	P=0.217, I <sup>2</sup> =3440%	P=0.195, I <sup>2</sup> =4047%	P=0.982
Musculoskeletal and connective tissue disorders		Moderate	1.2% (0.3, 4.5)	0%	P=0.093, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.012 (-0.004, 0.028)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.626

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Musculoskeletal and connective tissue disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Musculoskeletal and connective tissue disorders	Pain in extremity		2.9% (1.2, 6.8)	3.3% (1.1, 9.7)	P=0.640, I <sup>2</sup> =0%	P=0.041, I <sup>2</sup> =0%							P=0.829

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Musculoskeletal and connective tissue disorders	Pain in extremity	Mild	2.3% (0.9, 6.0)	3.3% (1.1, 9.7)	P=0.991, I <sup>2</sup> =0%	P=0.041, I <sup>2</sup> =0%	0.698 (0.153, 3.195)	0.705 (0.160, 3.103) 0.644	-0.010 (-0.053 - 0.033)	P=0.250, I <sup>2</sup> =2457%	P=0.253, I <sup>2</sup> =2346%	P=0.156, I <sup>2</sup> =5019%	P=0.971
Musculoskeletal and connective tissue disorders	Pain in extremity	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Musculoskeletal and connective tissue disorders	Pain in extremity	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Musculoskel etal and connective tissue disorders	Arthralgia		4.0% (1.9, 8.2)	1.1% (0.2, 7.4)	P=0.234 , I <sup>2</sup> =22.2 %	P=0.241 , I <sup>2</sup> =0%							P=0.363
Musculoskel etal and connective tissue disorders	Arthralgia	Mild	4.0% (1.9, 8.2)	1.1% (0.2, 7.4)	P=0.234 , I <sup>2</sup> =22.2 %	P=0.241 , I <sup>2</sup> =0%	3.889 (0.465, 32.547)	3.721 (0.466, 29.696) 0.215	0.030 (-0.006 - 0.066)	P=0.69 8, I <sup>2</sup> =0%	P=0.70 2, I <sup>2</sup> =0%	P=0.57 6, I <sup>2</sup> =0%	P=0.363
Musculoskel etal and connective tissue disorders	Arthralgia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Musculoskeletal and connective tissue disorders	Arthralgia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Musculoskeletal and connective tissue disorders	Musculoskeletal pain		1.2% (0.3, 4.5)	0%	P=0.093, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.626
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Musculoskeletal and connective tissue disorders	Neck pain		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.486

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Musculoskeletal and connective tissue disorders	Neck pain	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.486
Musculoskeletal and connective tissue disorders	Neck pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Musculoskeletal and connective tissue disorders	Neck pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Musculoskeletal and connective tissue disorders	Arthritis reactive		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769
Musculoskeletal and connective tissue disorders	Arthritis reactive	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Musculoskeletal and connective tissue disorders	Arthritis reactive	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Musculoskeletal and connective tissue disorders	Arthritis reactive	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Musculoskeletal and connective tissue disorders	Back pain		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Musculoskeletal and connective tissue disorders	Back pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Musculoskeletal and connective tissue disorders	Back pain	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Musculoskeletal and connective tissue disorders	Back pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Musculoskeletal and connective tissue disorders	Neck mass		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769
Musculoskeletal and connective tissue disorders	Neck mass	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Musculoskeletal and connective tissue disorders	Neck mass	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Musculoskeletal and connective tissue disorders	Neck mass	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Musculoskeletal and connective tissue disorders	Pain in jaw		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Musculoskeletal and connective tissue disorders	Pain in jaw	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Musculoskeletal and connective tissue disorders	Pain in jaw	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Musculoskeletal and connective tissue disorders	Pain in jaw	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Musculoskeletal and connective tissue disorders	Synovial cyst		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.681
Musculoskeletal and connective tissue disorders	Synovial cyst	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.681
Musculoskeletal and connective tissue disorders	Synovial cyst	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Musculoskeletal and connective tissue disorders	Synovial cyst	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Musculoskeletal and connective tissue disorders	Scoliosis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.670
Musculoskeletal and connective tissue disorders	Scoliosis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.670

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Musculoskeletal and connective tissue disorders	Scoliosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Musculoskeletal and connective tissue disorders	Scoliosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Metabolism and nutrition disorders			7.5% (4.4, 12.5)	8.8% (4.5, 16.6)	P=0.001, I <sup>2</sup> =83.7%	P=0.001, I <sup>2</sup> =0%							P=0.829

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Metabolism and nutrition disorders		Mild	7.5% (4.4, 12.5)	8.8% (4.5, 16.6)	P=0.001, I <sup>2</sup> =83.7%	P=0.001, I <sup>2</sup> =0%	0.817 (0.314, 2.126)	0.842 (0.375, 1.892) 0.677	-0.014 (-0.082, 0.054)	P=0.642, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	P=0.282, I <sup>2</sup> =1353%	P=0.829
Metabolism and nutrition disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Metabolism and nutrition disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Metabolism and nutrition disorders	Hypertriglyceridaemia		4.0% (1.9, 8.2)	2.2% (0.6, 8.4)	P=0.002, I <sup>2</sup> =0%	P=0.091, I <sup>2</sup> =0%							P=0.543
Metabolism and nutrition disorders	Hypertriglyceridaemia	Mild	4.0% (1.9, 8.2)	2.2% (0.6, 8.4)	P=0.002, I <sup>2</sup> =0%	P=0.091, I <sup>2</sup> =0%	1.881 (0.374, 9.455)	1.810 (0.392, 8.358) 0.447	0.018 (-0.023, 0.059)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.543
Metabolism and nutrition disorders	Hypertriglyceridaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Metabolism and nutrition disorders	Hypertriglyceridaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Metabolism and nutrition disorders	Hypercholesterolaemia		1.7% (0.6, 5.2)	3.3% (1.1, 9.7)	P=0.041, I <sup>2</sup> =0%	P=0.037, I <sup>2</sup> =0%							P=0.932
Metabolism and nutrition disorders	Hypercholesterolaemia	Mild	1.7% (0.6, 5.2)	3.3% (1.1, 9.7)	P=0.041, I <sup>2</sup> =0%	P=0.037, I <sup>2</sup> =0%	0.500 (0.097, 2.584)	0.517 (0.109, 2.460)	-0.016 (-0.057, 0.025)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.932
Metabolism and nutrition disorders	Hypercholesterolaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Metabolism and nutrition disorders	Hypercholesterolaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Metabolism and nutrition disorders	Decreased appetite		1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.096, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.827
Metabolism and nutrition disorders	Decreased appetite	Mild	1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.096, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	1.035 (0.091, 11.735)	1.034 (0.096, 11.103) 0.978	0.000 (-0.026 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.827
Metabolism and nutrition disorders	Decreased appetite	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Metabolism and nutrition disorders	Decreased appetite	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Metabolism and nutrition disorders	Hyperuricaemia		1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.096, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.827
Metabolism and nutrition disorders	Hyperuricaemia	Mild	1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.096, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	1.035 (0.091, 11.735)	1.034 (0.096, 11.103) 0.978	0.000 (-0.026 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.827

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Metabolism and nutrition disorders	Hyperuricaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Metabolism and nutrition disorders	Hyperuricaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Metabolism and nutrition disorders	Polydipsia		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769
Metabolism and nutrition disorders	Polydipsia	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Metabolism and nutrition disorders	Polydipsia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Metabolism and nutrition disorders	Polydipsia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Metabolism and nutrition disorders	Calcium deficiency		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.678

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Metabolism and nutrition disorders	Calcium deficiency	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678
Metabolism and nutrition disorders	Calcium deficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Metabolism and nutrition disorders	Calcium deficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Metabolism and nutrition disorders	Hyperglycaemia		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.678

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Metabolism and nutrition disorders	Hyperglycaemia	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678
Metabolism and nutrition disorders	Hyperglycaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Metabolism and nutrition disorders	Hyperglycaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Metabolism and nutrition disorders	Hyperlipidaemia		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.678
Metabolism and nutrition disorders	Hyperlipidaemia	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678
Metabolism and nutrition disorders	Hyperlipidaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Metabolism and nutrition disorders	Hyperlipidaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Endocrine disorders			4.6% (2.3, 9.0)	6.6% (3.0, 13.9)	P=0.135, I <sup>2</sup> =48.6%	P=0.003, I <sup>2</sup> =0%							P=0.701
Endocrine disorders		Mild	3.5% (1.6, 7.5)	6.6% (3.0, 13.9)	P=0.394, I <sup>2</sup> =0%	P=0.003, I <sup>2</sup> =0%	0.508 (0.158, 1.636)	0.531 (0.177, 1.589) 0.258	-0.031 (-0.088 - 0.027)	P=0.211, I <sup>2</sup> =361%	P=0.223, I <sup>2</sup> =327%	P=0.022, I <sup>2</sup> =808%	P=0.531
Endocrine disorders		Moderate	1.2% (0.3, 4.5)	0%	P=0.093, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.012 (-0.004 - 0.028)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.626
Endocrine disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Endocrine disorders	Secondary hypothyroidism		2.3% (0.9, 6.0)	3.3% (1.1, 9.7)	P=0.017, I <sup>2</sup> =0%	P=0.041, I <sup>2</sup> =0%							P=0.428
Endocrine disorders	Secondary hypothyroidism	Mild	1.7% (0.6, 5.2)	3.3% (1.1, 9.7)	P=0.039, I <sup>2</sup> =0%	P=0.041, I <sup>2</sup> =0%	0.518 (0.100, 2.676)	0.535 (0.112, 2.545) 0.432	-0.015 (-0.056, 0.026)	P=1.00, I <sup>2</sup> =0%	P=1.00, I <sup>2</sup> =0%	P=1.00, I <sup>2</sup> =0%	P=0.336
Endocrine disorders	Secondary hypothyroidism	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006, 0.017)	P=1.00, I <sup>2</sup> =0%	P=1.00, I <sup>2</sup> =0%	P=1.00, I <sup>2</sup> =0%	P=0.769
Endocrine disorders	Secondary hypothyroidism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Endocrine disorders	Hypothyroidism		1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.096, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.904
Endocrine disorders	Hypothyroidism	Mild	1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.096, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	1.047 (0.094, 11.644)	1.047 (0.093, 11.752) 0.971	0.001 (-0.026, 0.027)	P=0.215, I <sup>2</sup> =3506%	P=0.216, I <sup>2</sup> =3463%	P=0.219, I <sup>2</sup> =3395%	P=0.904
Endocrine disorders	Hypothyroidism	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Endocrine disorders	Hypothyroidism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Endocrine disorders	Diabetes insipidus		0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.949
Endocrine disorders	Diabetes insipidus	Mild	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	0.529 (0.032, 8.665)	0.535 (0.034, 8.355)	-0.005 (-0.029, 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.949
Endocrine disorders	Diabetes insipidus	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Endocrine disorders	Diabetes insipidus	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Endocrine disorders	Secondary adrenocortical insufficiency		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.422

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Endocrine disorders	Secondary adrenocortical insufficiency	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.422
Endocrine disorders	Secondary adrenocortical insufficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Endocrine disorders	Secondary adrenocortical insufficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Endocrine disorders	Adrenal insufficiency		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Endocrine disorders	Adrenal insufficiency	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Endocrine disorders	Adrenal insufficiency	Moderate	0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.769
Endocrine disorders	Adrenal insufficiency	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Endocrine disorders	Precocious puberty		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.773

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Endocrine disorders	Precocious puberty	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.773
Endocrine disorders	Precocious puberty	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Endocrine disorders	Precocious puberty	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Blood and lymphatic system disorders			7.5% (4.4, 12.5)	4.4% (1.7, 11.1)	P=0.756, I <sup>2</sup> =0%	P=0.982, I <sup>2</sup> =0%							P=0.480

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Blood and lymphatic system disorders		Mild	5.8% (3.1, 10.4)	4.4% (1.7, 11.1)	P=0.985, I <sup>2</sup> =0%	P=0.982, I <sup>2</sup> =0%	1.334 (0.407, 4.379)	1.315 (0.424, 4.076) 0.635	0.014 (-0.041 - 0.068)	P=0.977, I <sup>2</sup> =0%	P=0.977, I <sup>2</sup> =0%	P=0.977, I <sup>2</sup> =0%	P=0.597
Blood and lymphatic system disorders		Moderate	1.7% (0.6, 5.2)	0%	P=0.550, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.017 (-0.002 - 0.037)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.585, I <sup>2</sup> =0%	P=0.480
Blood and lymphatic system disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Blood and lymphatic system disorders	Anaemia		0.6% (0.1, 4.0)	3.3% (1.1, 9.7)	P=0.236, I <sup>2</sup> =0%	P=0.541, I <sup>2</sup> =0%							P=0.624

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Blood and lymphatic system disorders	Anaemia	Mild	0.6% (0.1, 4.0)	3.3% (1.1, 9.7)	P=0.236, I <sup>2</sup> =0%	P=0.541, I <sup>2</sup> =0%	0.174 (0.018, 1.674)	0.177 (0.019, 1.660) 0.129	-0.027 (-0.066, 0.011)	P=0.390, I <sup>2</sup> =0%	P=0.390, I <sup>2</sup> =0%	P=0.348, I <sup>2</sup> =0%	P=0.624
Blood and lymphatic system disorders	Anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Blood and lymphatic system disorders	Anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Blood and lymphatic system disorders	Iron deficiency anaemia		1.7% (0.6, 5.2)	0%	P=0.039, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.536
Blood and lymphatic system disorders	Iron deficiency anaemia	Mild	1.2% (0.3, 4.5)	0%	P=0.093, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.012 (-0.004 - 0.028)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.626
Blood and lymphatic system disorders	Iron deficiency anaemia	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Blood and lymphatic system disorders	Iron deficiency anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Blood and lymphatic system disorders	Lymphaden opathy		0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%							P=0.949
Blood and lymphatic system disorders	Lymphaden opathy	Mild	0%	1.1% (0.2, 7.4)	P=1.000 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.011 (-0.032 - 0.010)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.681
Blood and lymphatic system disorders	Lymphaden opathy	Moderate	0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Blood and lymphatic system disorders	Lymphaden opathy	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Blood and lymphatic system disorders	Neutropenia		1.2% (0.3, 4.5)	0%	P=0.093 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.626
Blood and lymphatic system disorders	Neutropenia	Mild	1.2% (0.3, 4.5)	0%	P=0.093 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.012 (-0.004 - 0.028)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.626
Blood and lymphatic system disorders	Neutropenia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Blood and lymphatic system disorders	Neutropenia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Blood and lymphatic system disorders	Granulocytopenia		1.2% (0.3, 4.5)	0%	P=0.096, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.629
Blood and lymphatic system disorders	Granulocytopenia	Mild	1.2% (0.3, 4.5)	0%	P=0.096, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.011 (-0.004 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.629

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Blood and lymphatic system disorders	Granulocytopenia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Blood and lymphatic system disorders	Granulocytopenia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Blood and lymphatic system disorders	Lymphadenitis		1.2% (0.3, 4.5)	0%	P=0.096, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.629
Blood and lymphatic system disorders	Lymphadenitis	Mild	1.2% (0.3, 4.5)	0%	P=0.096, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.011 (-0.004 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.629

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Blood and lymphatic system disorders	Lymphadenitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Blood and lymphatic system disorders	Lymphadenitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Blood and lymphatic system disorders	Hypochromic anaemia		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Blood and lymphatic system disorders	Hypochromic anaemia	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Blood and lymphatic system disorders	Hypochromic anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Blood and lymphatic system disorders	Hypochromic anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Blood and lymphatic system disorders	Thymus disorder		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Blood and lymphatic system disorders	Thymus disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Blood and lymphatic system disorders	Thymus disorder	Moderate	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Blood and lymphatic system disorders	Thymus disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Immune system disorders			4.0% (1.9, 8.2)	3.3% (1.1, 9.7)	P=0.041, I <sup>2</sup> =65.7%	P=0.566, I <sup>2</sup> =0%							P=0.960



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Immune system disorders		Mild	3.5% (1.6, 7.5)	3.3% (1.1, 9.7)	P=0.080, I <sup>2</sup> =56.1%	P=0.566, I <sup>2</sup> =0%	1.065 (0.259, 4.378)	1.062 (0.274, 4.119) 0.931	0.002 (-0.044, 0.048)	P=0.557, I <sup>2</sup> =0%	P=0.558, I <sup>2</sup> =0%	P=0.544, I <sup>2</sup> =0%	P=0.958
Immune system disorders		Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006, 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Immune system disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Immune system disorders	Seasonal allergy		1.7% (0.6, 5.2)	1.1% (0.2, 7.4)	P=0.039, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.964

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Immune system disorders	Seasonal allergy	Mild	1.7% (0.6, 5.2)	1.1% (0.2, 7.4)	P=0.039, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	1.627 (0.164, 16.095)	1.605 (0.172, 14.993) 0.678	0.007 (-0.022 - 0.035)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.964
Immune system disorders	Seasonal allergy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Immune system disorders	Seasonal allergy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Immune system disorders	Hypersensitivity		0.6% (0.1, 4.0)	2.2% (0.6, 8.4)	P=0.236, I <sup>2</sup> =0%	P=0.987, I <sup>2</sup> =0%							P=0.737

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Immune system disorders	Hypersensitivity	Mild	0%	2.2% (0.6, 8.4)	P=1.000, I <sup>2</sup> =0%	P=0.987, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.022 (-0.052 - 0.008)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.811, I <sup>2</sup> =0%	P=0.501
Immune system disorders	Hypersensitivity	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Immune system disorders	Hypersensitivity	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Immune system disorders	Allergy to animal		1.2% (0.3, 4.5)	0%	P=0.093, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.626

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Immune system disorders	Allergy to animal	Mild	1.2% (0.3, 4.5)	0%	P=0.093, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.012 (-0.004 - 0.028)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.626
Immune system disorders	Allergy to animal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Immune system disorders	Allergy to animal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Immune system disorders	Food allergy		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Immune system disorders	Food allergy	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Immune system disorders	Food allergy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Immune system disorders	Food allergy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Reproductive system and breast disorders			2.9% (1.2, 6.8)	2.2% (0.6, 8.4)	P=0.008, I <sup>2</sup> =0%	P=0.096, I <sup>2</sup> =0%							P=0.837

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Reproductive system and breast disorders		Mild	2.9% (1.2, 6.8)	2.2% (0.6, 8.4)	P=0.008, I <sup>2</sup> =0%	P=0.096, I <sup>2</sup> =0%	1.308 (0.253, 6.767)	1.308 (0.251, 6.824) 0.75	0.007 (-0.033, 0.046)	P=0.054, I <sup>2</sup> =731%	P=0.056, I <sup>2</sup> =725%	P=0.028, I <sup>2</sup> =792%	P=0.837
Reproductive system and breast disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Reproductive system and breast disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Reproductive system and breast disorders	Penile adhesion		0%	2.2% (0.6, 8.4)	P=1.000, I <sup>2</sup> =0%	P=0.096, I <sup>2</sup> =0%							P=0.545

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Reproductive system and breast disorders	Penile adhesion	Mild	0%	2.2% (0.6, 8.4)	P=1.000, I <sup>2</sup> =0%	P=0.096, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.022 (-0.052 - 0.008)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.545
Reproductive system and breast disorders	Penile adhesion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Reproductive system and breast disorders	Penile adhesion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Reproductive system and breast disorders	Gynaecomastia		1.2% (0.3, 4.5)	0%	P=0.096, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.629
Reproductive system and breast disorders	Gynaecomastia	Mild	1.2% (0.3, 4.5)	0%	P=0.096, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.011 (-0.004 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.629
Reproductive system and breast disorders	Gynaecomastia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Reproductive system and breast disorders	Gynaecomastia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Reproductiv e system and breast disorders	Genital discomfort		0%	1.1% (0.2, 7.4)	P=1.000 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%							P=0.681
Reproductiv e system and breast disorders	Genital discomfort	Mild	0%	1.1% (0.2, 7.4)	P=1.000 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.681
Reproductiv e system and breast disorders	Genital discomfort	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Reproductiv e system and breast disorders	Genital discomfort	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Reproductiv e system and breast disorders	Balanoposth itis		0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.771
Reproductiv e system and breast disorders	Balanoposth itis	Mild	0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.771
Reproductiv e system and breast disorders	Balanoposth itis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Reproductiv e system and breast disorders	Balanoposth itis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Reproductiv e system and breast disorders	Pelvic fluid collection		0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.771
Reproductiv e system and breast disorders	Pelvic fluid collection	Mild	0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Reproductiv e system and breast disorders	Pelvic fluid collection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Reproductiv e system and breast disorders	Pelvic fluid collection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Reproductiv e system and breast disorders	Testicular appendage torsion		0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.771
Reproductiv e system and breast disorders	Testicular appendage torsion	Mild	0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Reproductive system and breast disorders	Testicular appendage torsion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Reproductive system and breast disorders	Testicular appendage torsion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Ear and labyrinth disorders			1.7% (0.6, 5.2)	1.1% (0.2, 7.4)	P=0.550, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%							P=0.810

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Ear and labyrinth disorders		Mild	1.7% (0.6, 5.2)	1.1% (0.2, 7.4)	P=0.550 , I <sup>2</sup> =0%	P=0.233 , I <sup>2</sup> =0%	1.581 (0.164, 15.265)	1.575 (0.167, 14.836) 0.692	0.006 (-0.023 - 0.035)	P=0.38 6, I <sup>2</sup> =0%	P=0.38 5, I <sup>2</sup> =0%	P=0.39 3, I <sup>2</sup> =0%	P=0.810
Ear and labyrinth disorders		Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Ear and labyrinth disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Ear and labyrinth disorders	Ear pain		1.2% (0.3, 4.5)	0%	P=0.093 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.957
Ear and labyrinth disorders	Ear pain	Mild	1.2% (0.3, 4.5)	0%	P=0.093 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.012 (-0.004 - 0.028)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.957

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Ear and labyrinth disorders	Ear pain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Ear and labyrinth disorders	Ear pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Ear and labyrinth disorders	Cerumen impaction		0%	1.1% (0.2, 7.4)	P=1.000 , I <sup>2</sup> =0%	P=0.233 , I <sup>2</sup> =0%							P=0.678
Ear and labyrinth disorders	Cerumen impaction	Mild	0%	1.1% (0.2, 7.4)	P=1.000 , I <sup>2</sup> =0%	P=0.233 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.678

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Ear and labyrinth disorders	Cerumen impaction	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Ear and labyrinth disorders	Cerumen impaction	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Ear and labyrinth disorders	Motion sickness		0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.771
Ear and labyrinth disorders	Motion sickness	Mild	0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.771



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Ear and labyrinth disorders	Motion sickness	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Ear and labyrinth disorders	Motion sickness	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Psychiatric disorders			2.3% (0.9, 6.0)	1.1% (0.2, 7.4)	P=0.017 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%							P=0.574
Psychiatric disorders		Mild	1.7% (0.6, 5.2)	1.1% (0.2, 7.4)	P=0.039 , I <sup>2</sup> =0%	P=0.241 , I <sup>2</sup> =0%	1.627 (0.164, 16.095)	1.605 (0.172, 14.993) 0.678	0.007 (-0.022 - 0.035)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.674

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Psychiatric disorders		Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Psychiatric disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Psychiatric disorders	Attention deficit/hyperactivity disorder		0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.949
Psychiatric disorders	Attention deficit/hyperactivity disorder	Mild	0.6% (0.1, 4.0)	1.1% (0.2, 7.4)	P=0.236, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	0.529 (0.032, 8.665)	0.535 (0.034, 8.355) 0.655	-0.005 (-0.029 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.949
Psychiatric disorders	Attention deficit/hyperactivity disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Psychiatric disorders	Attention deficit/hyperactivity disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Psychiatric disorders	Affect lability		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769
Psychiatric disorders	Affect lability	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Psychiatric disorders	Affect lability	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Psychiatric disorders	Affect lability	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Psychiatric disorders	Depressive symptom		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769
Psychiatric disorders	Depressive symptom	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Psychiatric disorders	Depressive symptom	Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Psychiatric disorders	Depressive symptom	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Psychiatric disorders	Enuresis		0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.769
Psychiatric disorders	Enuresis	Mild	0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.769
Psychiatric disorders	Enuresis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Psychiatric disorders	Enuresis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Cardiac disorders			2.3% (0.9, 6.0)	0%	P=0.991, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.396
Cardiac disorders		Mild	1.7% (0.6, 5.2)	0%	P=0.563, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.017 (-0.002 - 0.037)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.602, I <sup>2</sup> =0%	P=0.481
Cardiac disorders		Moderate	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Cardiac disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Cardiac disorders	Sinoatrial block		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769
Cardiac disorders	Sinoatrial block	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Cardiac disorders	Sinoatrial block	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Cardiac disorders	Sinoatrial block	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Cardiac disorders	Sinus tachycardia		0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.769
Cardiac disorders	Sinus tachycardia	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Cardiac disorders	Sinus tachycardia	Moderate	0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.769
Cardiac disorders	Sinus tachycardia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Cardiac disorders	Tachycardia		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769
Cardiac disorders	Tachycardia	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Cardiac disorders	Tachycardia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Cardiac disorders	Tachycardia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Cardiac disorders	Myocarditis		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Cardiac disorders	Myocarditis	Mild	0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.771
Cardiac disorders	Myocarditis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Cardiac disorders	Myocarditis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Cardiac disorders	Wandering pacemaker		0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Cardiac disorders	Wandering pacemaker	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Cardiac disorders	Wandering pacemaker	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Cardiac disorders	Wandering pacemaker	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			1.2% (0.3, 4.5)	0%	P=0.093, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.562
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Mild	1.2% (0.3, 4.5)	0%	P=0.093, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.012 (-0.004 - 0.028)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.562

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.718

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma		0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.769



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Renal and urinary disorders			1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.093 , I <sup>2</sup> =0%	P=0.233 , I <sup>2</sup> =0%							P=0.904
Renal and urinary disorders		Mild	1.2% (0.3, 4.5)	1.1% (0.2, 7.4)	P=0.093 , I <sup>2</sup> =0%	P=0.233 , I <sup>2</sup> =0%	1.057 (0.097, 11.555)	1.057 (0.098, 11.454) 0.963	0.001 (-0.026 - 0.028)	P=0.204, I <sup>2</sup> =381 5%	P=0.205, I <sup>2</sup> =377 4%	P=0.210, I <sup>2</sup> =364 1%	P=0.904

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Renal and urinary disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Renal and urinary disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Renal and urinary disorders	Pollakiuria		0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.769
Renal and urinary disorders	Pollakiuria	Mild	0.6% (0.1, 4.0)	0%	P=0.236, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Renal and urinary disorders	Pollakiuria	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Renal and urinary disorders	Pollakiuria	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Renal and urinary disorders	Polyuria		0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.769
Renal and urinary disorders	Polyuria	Mild	0.6% (0.1, 4.0)	0%	P=0.236 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.769

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Renal and urinary disorders	Polyuria	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Renal and urinary disorders	Polyuria	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Renal and urinary disorders	Nocturia		0%	1.1% (0.2, 7.4)	P=1.000 , I <sup>2</sup> =0%	P=0.233 , I <sup>2</sup> =0%							P=0.678
Renal and urinary disorders	Nocturia	Mild	0%	1.1% (0.2, 7.4)	P=1.000 , I <sup>2</sup> =0%	P=0.233 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.033 - 0.010)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.678
Renal and urinary disorders	Nocturia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Renal and urinary disorders	Nocturia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Vascular disorders			0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.797
Vascular disorders		Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.797
Vascular disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Vascular disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Vascular disorders	Hypotension		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.550
Vascular disorders	Hypotension	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.550
Vascular disorders	Hypotension	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Vascular disorders	Hypotension	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Vascular disorders	Cyanosis		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771
Vascular disorders	Cyanosis	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Vascular disorders	Cyanosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Vascular disorders	Cyanosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Congenital, familial and genetic disorders			1.2% (0.3, 4.5)	0%	P=0.096, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.629
Congenital, familial and genetic disorders		Mild	1.2% (0.3, 4.5)	0%	P=0.096, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.011 (-0.004 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.629
Congenital, familial and genetic disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Congenital, familial and genetic disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954
Congenital, familial and genetic disorders	Buried penis syndrome		0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.771
Congenital, familial and genetic disorders	Buried penis syndrome	Mild	0.6% (0.1, 4.0)	0%	P=0.240 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771
Congenital, familial and genetic disorders	Buried penis syndrome	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Male													
Congenital, familial and genetic disorders	Buried penis syndrome	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Congenital, familial and genetic disorders	Supernumerary teeth		0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.771
Congenital, familial and genetic disorders	Supernumerary teeth	Mild	0.6% (0.1, 4.0)	0%	P=0.240, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.006 (-0.006 - 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.771

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Congenital, familial and genetic disorders	Supernumerary teeth	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Congenital, familial and genetic disorders	Supernumerary teeth	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Hepatobiliary disorders			0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.681
Hepatobiliary disorders		Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.681

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Hepatobiliary disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Hepatobiliary disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Hepatobiliary disorders	Hepatomegaly		0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%							P=0.681
Hepatobiliary disorders	Hepatomegaly	Mild	0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.241, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.011 (-0.032 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.681
Hepatobiliary disorders	Hepatomegaly	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Male													
Hepatobiliary disorders	Hepatomegaly	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Any adverse event			84.4% (67.5, 93.3)	72.2% (48.1, 87.9)	P=0.975, I <sup>2</sup> =0%	P=0.182, I <sup>2</sup> =34%							
Any adverse event		Mild	62.5% (44.9, 77.3)	61.1% (37.9, 80.2)	P=0.156, I <sup>2</sup> =46.6%	P=0.033, I <sup>2</sup> =72%	1.136 (0.320, 4.027)	1.044 (0.677, 1.609) 0.846	0.026 (-0.237, 0.290)	P=0.398, I <sup>2</sup> =0%	P=0.319, I <sup>2</sup> =0%	P=0.341, I <sup>2</sup> =0%	
Any adverse event		Moderate	21.9% (10.8, 39.3)	11.1% (2.8, 35.2)	P=0.090, I <sup>2</sup> =54.7%	P=0.110, I <sup>2</sup> =0%	2.271 (0.386, 13.357)	1.870 (0.463, 7.554) 0.38	0.099 (-0.096, 0.294)	P=0.817, I <sup>2</sup> =0%	P=0.813, I <sup>2</sup> =0%	P=0.664, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Any adverse event		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations			56.3% (39.0, 72.1)	61.1% (37.9, 80.2)	P=0.341 , I <sup>2</sup> =0%	P=0.274 , I <sup>2</sup> =12%							
Infections and infestations		Mild	37.5% (22.7, 55.1)	55.6% (33.0, 76.0)	P=0.926 , I <sup>2</sup> =0%	P=0.132 , I <sup>2</sup> =52%	0.488 (0.151, 1.584)	0.682 (0.369, 1.260) 0.221	-0.175 (-0.460 - 0.109)	P=0.261, I <sup>2</sup> =2069%	P=0.351, I <sup>2</sup> =0%	P=0.231, I <sup>2</sup> =3044%	
Infections and infestations		Moderate	18.8% (8.7, 35.9)	5.6% (0.8, 30.7)	P=0.164 , I <sup>2</sup> =36%	P=0.269 , I <sup>2</sup> =0%	4.003 (0.418, 38.362)	3.213 (0.440, 23.458) 0.25	0.126 (-0.041 - 0.293)	P=0.660, I <sup>2</sup> =0%	P=0.705, I <sup>2</sup> =0%	P=0.475, I <sup>2</sup> =0%	



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Upper respiratory tract infection		15.6% (6.7, 32.5)	27.8% (12.1, 51.9)	P=0.001, I <sup>2</sup> =0%	P=0.001, I <sup>2</sup> =0%							
Infections and infestations	Upper respiratory tract infection	Mild	15.6% (6.7, 32.5)	27.8% (12.1, 51.9)	P=0.001, I <sup>2</sup> =0%	P=0.001, I <sup>2</sup> =0%	0.375 (0.061, 2.305)	0.615 (0.257, 1.472) 0.275	-0.103 (-0.302, 0.095)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Upper respiratory tract infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Upper respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Nasopharyngitis		3.1% (0.4, 19.1)	11.1% (2.8, 35.2)	P=0.302, I <sup>2</sup> =0%	P=0.867, I <sup>2</sup> =0%							
Infections and infestations	Nasopharyngitis	Mild	3.1% (0.4, 19.1)	11.1% (2.8, 35.2)	P=0.302, I <sup>2</sup> =0%	P=0.867, I <sup>2</sup> =0%	0.250 (0.020, 3.063)	0.271 (0.025, 2.953) 0.284	-0.081 (-0.238, 0.076)	P=0.615, I <sup>2</sup> =0%	P=0.609, I <sup>2</sup> =0%	P=0.627, I <sup>2</sup> =0%	
Infections and infestations	Nasopharyngitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Nasopharyngitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis		12.5% (4.8, 28.9)	11.1% (2.8, 35.2)	P=0.033, I <sup>2</sup> =0%	P=0.867, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis	Mild	9.4% (3.1, 25.4)	11.1% (2.8, 35.2)	P=0.068, I <sup>2</sup> =0%	P=0.867, I <sup>2</sup> =0%	0.795 (0.119, 5.321)	0.812 (0.143, 4.614) 0.814	-0.021 (-0.197, 0.156)	P=0.291, I <sup>2</sup> =1028%	P=0.297, I <sup>2</sup> =817%	P=0.302, I <sup>2</sup> =612%	
Infections and infestations	Pharyngitis	Moderate	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029, 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Pharyngitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection		6.3% (1.6, 21.8)	5.6% (0.8, 30.7)	P=0.140, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection	Mild	3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	0.557 (0.033, 9.364)	0.557 (0.031, 9.949) 0.691	-0.024 (-0.146, 0.098)	P=0.352, I <sup>2</sup> =0%	P=0.361, I <sup>2</sup> =0%	P=0.311, I <sup>2</sup> =250%	
Infections and infestations	Respiratory tract infection	Moderate	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029, 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Bronchitis		3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.174, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%							
Infections and infestations	Bronchitis	Mild	3.1% (0.4, 19.1)	0%	P=0.174, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.029 - 0.095)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Bronchitis	Moderate	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Bronchitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Tonsillitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rhinitis		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rhinitis	Mild	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Rhinitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rhinitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Gastroenteritis		3.1% (0.4, 19.1)	11.1% (2.8, 35.2)	P=0.302, I <sup>2</sup> =0%	P=0.867, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis	Mild	3.1% (0.4, 19.1)	11.1% (2.8, 35.2)	P=0.302, I <sup>2</sup> =0%	P=0.867, I <sup>2</sup> =0%	0.250 (0.020, 3.063)	0.271 (0.025, 2.953) 0.284	-0.081 (-0.238, 0.076)	P=0.615, I <sup>2</sup> =0%	P=0.609, I <sup>2</sup> =0%	P=0.627, I <sup>2</sup> =0%	
Infections and infestations	Gastroenteritis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Pharyngitis streptococcal		0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis streptococcal	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pharyngitis streptococcal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis streptococcal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Sinusitis		0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%							
Infections and infestations	Sinusitis	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Sinusitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinusitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pneumonia		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Pneumonia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pneumonia	Moderate	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pneumonia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Ear infection		3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Ear infection	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Ear infection	Moderate	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Ear infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral infection		9.4% (3.1, 25.4)	0%	P=0.068, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Viral infection	Mild	6.3% (1.6, 21.8)	0%	P=0.140, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.060 (-0.023 - 0.142)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Viral infection	Moderate	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Viral infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection viral		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Respiratory tract infection viral	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection viral	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection viral	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Gastroenteritis viral		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis viral	Mild	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Gastroenteritis viral	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis viral	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis media acute		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Otitis media acute	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis media acute	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis media acute	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Varicella		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Varicella	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Varicella	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Varicella	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis		3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.054 (-0.158 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Conjunctivitis	Moderate	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Conjunctivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Enteritis infectious		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Enteritis infectious	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Enteritis infectious	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Enteritis infectious	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Influenza		3.1% (0.4, 19.1)	0%	P=0.174, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Influenza	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Influenza	Moderate	3.1% (0.4, 19.1)	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.029 - 0.095)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Influenza	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Enterobiasis		6.3% (1.6, 21.8)	0%	P=0.140, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Enterobiasis	Mild	6.3% (1.6, 21.8)	0%	P=0.140, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.060 (-0.023 - 0.142)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Enterobiasis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Enterobiasis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Herpangina		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Herpangina	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Herpangina	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Herpangina	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis media		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis media	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis media	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis media	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Periodontitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Periodontitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Periodontitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Periodontitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Helminthic infection		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Helminthic infection	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Helminthic infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Helminthic infection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pulpitis dental		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Pulpitis dental	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pulpitis dental	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pulpitis dental	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Viral upper respiratory tract infection		0%	5.6% (0.8, 30.7)	P=1.000 , I <sup>2</sup> =0%	P=0.269 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Viral upper respiratory tract infection	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Viral upper respiratory tract infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral upper respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hordeolum		0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Hordeolum	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Hordeolum	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hordeolum	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngoton sillitis		3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Pharyngoton sillitis	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pharyngoton sillitis	Moderate	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pharyngoton sillitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Urinary tract infection		0%	11.1% (2.8, 35.2)	P=1.000, I <sup>2</sup> =0%	P=0.867, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Urinary tract infection	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.054 (-0.158 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Urinary tract infection	Moderate	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Urinary tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hand-foot-and-mouth disease		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hand-foot-and-mouth disease	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Hand-foot-and-mouth disease	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hand-foot-and-mouth disease	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Laryngitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Laryngitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Laryngitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Laryngitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Oral herpes		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Oral herpes	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Oral herpes	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Oral herpes	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Appendicitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Appendicitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Appendicitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Appendicitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Atypical pneumonia		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Atypical pneumonia	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Atypical pneumonia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Atypical pneumonia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Conjunctivitis bacterial		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis bacterial	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis bacterial	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis bacterial	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Laryngitis viral		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Laryngitis viral	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Laryngitis viral	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Laryngitis viral	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Molluscum contagiosum		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Molluscum contagiosum	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Molluscum contagiosum	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Molluscum contagiosum	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis externa		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis externa	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Otitis externa	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis externa	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rotavirus infection		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rotavirus infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rotavirus infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Rotavirus infection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tinea pedis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tinea pedis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tinea pedis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tinea pedis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Tooth abscess		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tooth abscess	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tooth abscess	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tooth abscess	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Croup infectious		0%	7.1% (1.8, 24.5)	P=1.000, I <sup>2</sup> =0%	P=0.495, I <sup>2</sup> =0%							
Infections and infestations	Croup infectious	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Croup infectious	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Croup infectious	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Cystitis		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Cystitis	Mild	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Cystitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Cystitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Eczema infected		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Eczema infected	Mild	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Eczema infected	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Eczema infected	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Infected bite		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Infected bite	Mild	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Infected bite	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Infected bite	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Vulvitis		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Vulvitis	Mild	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Vulvitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Vulvitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Abscess limb		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Abscess limb	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Abscess limb	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Abscess limb	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Bacterial infection		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Bacterial infection	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Bacterial infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Bacterial infection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Chronic tonsillitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Chronic tonsillitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Chronic tonsillitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Chronic tonsillitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Folliculitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Folliculitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Folliculitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Folliculitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Gastrointestinal bacterial infection		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastrointestinal bacterial infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastrointestinal bacterial infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastrointestinal bacterial infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Herpes virus infection		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Herpes virus infection	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Herpes virus infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Herpes virus infection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Infectious mononucleosis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Infectious mononucleosis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Infectious mononucleosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Infectious mononucleosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Mumps		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Mumps	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Mumps	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Mumps	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Myringitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Myringitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Myringitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Myringitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Peritonsillar abscess		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Peritonsillar abscess	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Peritonsillar abscess	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Peritonsillar abscess	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Sinobronchitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinobronchitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinobronchitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinobronchitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Infections and infestations	Subcutaneous abscess		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Subcutaneous abscess	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Subcutaneous abscess	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Subcutaneous abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis bacterial		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Tonsillitis bacterial	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis bacterial	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis bacterial	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tracheitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tracheitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Tracheitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tracheitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Chronic sinusitis		3.1% (0.4, 19.1)	0%	P=0.174 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Chronic sinusitis	Mild	3.1% (0.4, 19.1)	0%	P=0.174 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.029 - 0.095)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Infections and infestations	Chronic sinusitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Chronic sinusitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigations			18.8% (8.7, 35.9)	27.8% (12.1, 51.9)	P=0.606 , I <sup>2</sup> =0%	P=0.055 , I <sup>2</sup> =67%							
Investigations		Mild	18.8% (8.7, 35.9)	27.8% (12.1, 51.9)	P=0.606 , I <sup>2</sup> =0%	P=0.055 , I <sup>2</sup> =67%	0.612 (0.153, 2.452)	0.695 (0.248, 1.946) 0.489	-0.083 (-0.325 - 0.159)	P=0.268, I <sup>2</sup> =1851%	P=0.315, I <sup>2</sup> =99%	P=0.156, I <sup>2</sup> =5031%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood glucose increased		0%	22.2% (8.6, 46.5)	P=1.000, I <sup>2</sup> =0%	P=0.005, I <sup>2</sup> =0%							
Investigations	Blood glucose increased	Mild	0%	22.2% (8.6, 46.5)	P=1.000, I <sup>2</sup> =0%	P=0.005, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.215 (-0.406 - -0.024)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood glucose increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Blood glucose increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Insulin-like growth factor increased		9.4% (3.1, 25.4)	5.6% (0.8, 30.7)	P=0.015, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%							
Investigations	Insulin-like growth factor increased	Mild	9.4% (3.1, 25.4)	5.6% (0.8, 30.7)	P=0.015, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	2.100 (0.179, 24.596)	1.846 (0.230, 14.848) 0.564	0.046 (-0.093, 0.184)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Insulin-like growth factor increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Insulin-like growth factor increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Low density lipoprotein increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Low density lipoprotein increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Low density lipoprotein increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Low density lipoprotein increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood alkaline phosphatase increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Blood alkaline phosphatase increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood alkaline phosphatase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood alkaline phosphatase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Eosinophil count increased		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Eosinophil count increased	Mild	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Eosinophil count increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Eosinophil count increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Blood iron increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Alanine aminotransferase increased		0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%							
Investigations	Alanine aminotransferase increased	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Alanine aminotransferase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Alanine aminotransferase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood phosphorus increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood phosphorus increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood phosphorus increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Blood phosphorus increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood uric acid increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood uric acid increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood uric acid increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Blood uric acid increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol decreased		3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.174, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%							
Investigations	Cortisol decreased	Mild	3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.174, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	0.583 (0.031, 10.863)	0.615 (0.044, 8.522) 0.717	-0.021 (-0.139, 0.097)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Cortisol decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Aspartate aminotransferase increased		0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%							
Investigations	Aspartate aminotransferase increased	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Aspartate aminotransferase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Aspartate aminotransferase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Blood triglycerides increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood triglycerides increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood triglycerides increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood triglycerides increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood glucose abnormal		0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Blood glucose abnormal	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.054 (-0.158 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood glucose abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood glucose abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Investigation s	Blood thyroid stimulating hormone increased		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood thyroid stimulating hormone increased	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood thyroid stimulating hormone increased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Blood thyroid stimulating hormone increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	White blood cell count decreased		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	White blood cell count decreased	Mild	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	White blood cell count decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	White blood cell count decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood urea increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood urea increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood urea increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Blood urea increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram T wave peaked		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram T wave peaked	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram T wave peaked	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram T wave peaked	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Tri-iodothyronine free increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Tri-iodothyronine free increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Tri-iodothyronine free increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Tri-iodothyronine free increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Blood iron decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Thyroxine decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Transaminases increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Transaminases increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Transaminases increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Transaminases increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cortisol decreased		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cortisol decreased	Mild	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Investigation s	Blood cortisol decreased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood cortisol decreased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Cortisol free urine decreased		3.1% (0.4, 19.1)	0%	P=0.302 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Cortisol free urine decreased	Mild	3.1% (0.4, 19.1)	0%	P=0.302 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Cortisol free urine decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol free urine decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Basophil count increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Basophil count increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Basophil count increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Basophil count increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Blood lactate dehydrogenase increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood lactate dehydrogenase increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood lactate dehydrogenase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Blood lactate dehydrogenase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood potassium increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood potassium increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood potassium increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood potassium increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Blood pressure increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood pressure increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood pressure increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood pressure increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Electrocardiogram ST segment abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram ST segment abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram ST segment abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram ST segment abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram high voltage		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Electrocardiogram high voltage	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram high voltage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram high voltage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Haemoglobin decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Haemoglobin decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Haemoglobin decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Haemoglobin decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Hepatic enzyme abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Hepatic enzyme increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Lipids increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Lipids increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Lipids increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Lipids increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Thyroid function test abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroid function test abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroid function test abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Thyroid function test abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine free decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine free decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine free decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine free decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Liver function test abnormal		0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%							
Investigations	Liver function test abnormal	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.054 (-0.158 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Liver function test abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Investigations	Liver function test abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders			28.1% (15.3, 45.8)	5.6% (0.8, 30.7)	P=0.784, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders		Mild	28.1% (15.3, 45.8)	5.6% (0.8, 30.7)	P=0.784, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	6.371 (0.751, 54.045)	4.957 (0.699, 35.168) 0.109	0.225 (0.035 - 0.416)	P=0.548, I <sup>2</sup> =0%	P=0.530, I <sup>2</sup> =0%	P=0.598, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Cough		21.9% (10.8, 39.3)	0%	P=0.318, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Cough	Mild	21.9% (10.8, 39.3)	0%	P=0.318, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.222 (0.078 - 0.366)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.354, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Cough	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Cough	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Mild	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Asthma		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Asthma	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Asthma	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Respiratory, thoracic and mediastinal disorders	Asthma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Respiratory disorder		3.1% (0.4, 19.1)	0%	P=0.302 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Mild	3.1% (0.4, 19.1)	0%	P=0.302 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Respiratory, thoracic and mediastinal disorders	Epistaxis		0%	5.6% (0.8, 30.7)	P=1.000 , I <sup>2</sup> =0%	P=0.269 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Epistaxis	Mild	0%	5.6% (0.8, 30.7)	P=1.000 , I <sup>2</sup> =0%	P=0.269 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Epistaxis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Respiratory, thoracic and mediastinal disorders	Epistaxis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal congestion		0%	5.6% (0.8, 30.7)	P=1.000 , I <sup>2</sup> =0%	P=0.269 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Mild	0%	5.6% (0.8, 30.7)	P=1.000 , I <sup>2</sup> =0%	P=0.269 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sinus congestion		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Wheezing		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Wheezing	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Wheezing	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Wheezing	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Allergic cough		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Allergic cough	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Allergic cough	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Allergic cough	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Laryngospasm		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Nasal obstruction		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Respiratory, thoracic and mediastinal disorders	Productive cough		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Productive cough	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Productive cough	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Respiratory, thoracic and mediastinal disorders	Productive cough	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders			25.0% (13.0, 42.6)	16.7% (5.5, 40.9)	P=0.835, I <sup>2</sup> =0%	P=0.668, I <sup>2</sup> =0%							
Gastrointestinal disorders		Mild	25.0% (13.0, 42.6)	11.1% (2.8, 35.2)	P=0.835, I <sup>2</sup> =0%	P=0.867, I <sup>2</sup> =0%	2.661 (0.498, 14.208)	2.250 (0.531, 9.537) 0.271	0.138 (-0.070, 0.347)	P=0.804, I <sup>2</sup> =0%	P=0.810, I <sup>2</sup> =0%	P=0.790, I <sup>2</sup> =0%	



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Gastrointestinal disorders		Moderate	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Diarrhoea		9.4% (3.1, 25.4)	5.6% (0.8, 30.7)	P=0.785, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%							
Gastrointestinal disorders	Diarrhoea	Mild	9.4% (3.1, 25.4)	5.6% (0.8, 30.7)	P=0.785, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	1.709 (0.164, 17.818)	1.634 (0.190, 14.039) 0.654	0.036 (-0.110 - 0.182)	P=0.700, I <sup>2</sup> =0%	P=0.694, I <sup>2</sup> =0%	P=0.768, I <sup>2</sup> =0%	
Gastrointestinal disorders	Diarrhoea	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Gastrointestinal disorders	Diarrhoea	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Vomiting		0%	11.1% (2.8, 35.2)	P=1.000, I <sup>2</sup> =0%	P=0.110, I <sup>2</sup> =0%							
Gastrointestinal disorders	Vomiting	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Vomiting	Moderate	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Gastrointestinal disorders	Vomiting	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Nausea		0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%							
Gastrointestinal disorders	Nausea	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Nausea	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Gastrointestinal disorders	Nausea	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal pain		6.3% (1.6, 21.8)	5.6% (0.8, 30.7)	P=0.782, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal pain	Mild	6.3% (1.6, 21.8)	5.6% (0.8, 30.7)	P=0.782, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	1.187 (0.096, 14.661)	1.172 (0.111, 12.384) 0.895	0.009 (-0.124, 0.142)	P=0.601, I <sup>2</sup> =0%	P=0.598, I <sup>2</sup> =0%	P=0.634, I <sup>2</sup> =0%	
Gastrointestinal disorders	Abdominal pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Gastrointestinal disorders	Abdominal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal pain upper		3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal pain upper	Mild	3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	0.500 (0.028, 8.952)	0.526 (0.037, 7.554) 0.637	-0.027 (-0.148 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Abdominal pain upper	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal pain upper	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Gastrointestinal disorders	Dyspepsia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Dyspepsia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Dyspepsia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Dyspepsia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Gastrointesti nal disorders	Constipation		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Constipation	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Constipation	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Constipation	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Toothache		3.1% (0.4, 19.1)	0%	P=0.174 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Gastrointestinal disorders	Toothache	Mild	3.1% (0.4, 19.1)	0%	P=0.174, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.029 - 0.095)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Toothache	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Toothache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal discomfort		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Gastrointesti nal disorders	Abdominal discomfort	Mild	3.1% (0.4, 19.1)	0%	P=0.302 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
Gastrointesti nal disorders	Abdominal discomfort	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Abdominal discomfort	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Enteritis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Enteritis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Gastrointestinal disorders	Enteritis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Enteritis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastrointestinal disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastrointestinal disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Gastrointestinal disorders	Gastrointestinal disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastrointestinal disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Aphthous ulcer		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Aphthous ulcer	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Aphthous ulcer	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Gastrointesti nal disorders	Aphthous ulcer	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastric disorder		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastric disorder	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastric disorder	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastric disorder	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Gastrointestinal disorders	Gastrointestinal motility disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastrointestinal motility disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastrointestinal motility disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastrointestinal motility disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Gastrointestinal disorders	Lip swelling		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Lip swelling	Mild	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Lip swelling	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Lip swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal distension		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Gastrointestinal disorders	Abdominal distension	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal distension	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal distension	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Noninfective gingivitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Gastrointesti nal disorders	Noninfective gingivitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Noninfective gingivitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Noninfective gingivitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions			12.5% (4.8, 28.9)	27.8% (12.1, 51.9)	P=0.485 , I <sup>2</sup> =0%	P=0.813 , I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions		Mild	12.5% (4.8, 28.9)	27.8% (12.1, 51.9)	P=0.485, I <sup>2</sup> =0%	P=0.813, I <sup>2</sup> =0%	0.361 (0.082, 1.591)	0.442 (0.135, 1.445) 0.177	-0.155 (-0.391, 0.080)	P=0.730, I <sup>2</sup> =0%	P=0.689, I <sup>2</sup> =0%	P=0.896, I <sup>2</sup> =0%	
General disorders and administration site conditions		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Pyrexia		12.5% (4.8, 28.9)	11.1% (2.8, 35.2)	P=0.485, I <sup>2</sup> =0%	P=0.110, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Pyrexia	Mild	12.5% (4.8, 28.9)	11.1% (2.8, 35.2)	P=0.485, I <sup>2</sup> =0%	P=0.110, I <sup>2</sup> =0%	1.095 (0.175, 6.856)	1.080 (0.229, 5.085) 0.922	0.009 (-0.173, 0.191)	P=0.600, I <sup>2</sup> =0%	P=0.597, I <sup>2</sup> =0%	P=0.613, I <sup>2</sup> =0%	
General disorders and administration site conditions	Pyrexia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Pyrexia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
General disorders and administrati on site conditions	Injection site pain		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site pain	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Injection site pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Injection site pruritus		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site pruritus	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site pruritus	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Injection site pruritus	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Fatigue		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Fatigue	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Fatigue	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Fatigue	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site swelling		0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site swelling	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.054 (-0.158 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Injection site swelling	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Injection site erythema		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site erythema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Injection site erythema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site erythema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site reaction		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Injection site reaction	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site reaction	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Injection site reaction	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Face oedema		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Face oedema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Face oedema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Face oedema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Gait disturbance		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Gait disturbance	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
General disorders and administrati on site conditions	Gait disturbance	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Gait disturbance	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Influenza like illness		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Influenza like illness	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Influenza like illness	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Influenza like illness	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site atrophy		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
General disorders and administrati on site conditions	Injection site atrophy	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site atrophy	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Injection site atrophy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site urticaria		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site urticaria	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Injection site urticaria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site urticaria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Medical device discomfort		0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%							
General disorders and administration site conditions	Medical device discomfort	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
General disorders and administrati on site conditions	Medical device discomfort	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Medical device discomfort	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Vaccination site pain		0%	5.6% (0.8, 30.7)	P=1.000 , I <sup>2</sup> =0%	P=0.269 , I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Vaccination site pain	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Vaccination site pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Vaccination site pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site bruising		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Injection site bruising	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site bruising	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site bruising	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Injection site haemorrhage		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site haemorrhage	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Injection site haemorrhage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site haemorrhage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Peripheral swelling		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Peripheral swelling	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Peripheral swelling	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Peripheral swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Pain		0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
General disorders and administration site conditions	Pain	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.054 (-0.158 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
General disorders and administrati on site conditions	Pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Nervous system disorders			6.3% (1.6, 21.8)	27.8% (12.1, 51.9)	P=0.782 , I <sup>2</sup> =0%	P=0.411 , I <sup>2</sup> =0%							
Nervous system disorders		Mild	6.3% (1.6, 21.8)	27.8% (12.1, 51.9)	P=0.782 , I <sup>2</sup> =0%	P=0.411 , I <sup>2</sup> =0%	0.174 (0.030, 1.022)	0.229 (0.049, 1.063) 0.06	-0.212 (-0.435 - 0.010)	P=0.796 , I <sup>2</sup> =0%	P=0.874 , I <sup>2</sup> =0%	P=0.508 , I <sup>2</sup> =0%	
Nervous system disorders		Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Nervous system disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Nervous system disorders	Headache		3.1% (0.4, 19.1)	16.7% (5.5, 40.9)	P=0.302, I <sup>2</sup> =0%	P=0.396, I <sup>2</sup> =0%							
Nervous system disorders	Headache	Mild	3.1% (0.4, 19.1)	16.7% (5.5, 40.9)	P=0.302, I <sup>2</sup> =0%	P=0.396, I <sup>2</sup> =0%	0.167 (0.016, 1.712)	0.182 (0.018, 1.793) 0.144	-0.135 (-0.318, 0.049)	P=0.413, I <sup>2</sup> =0%	P=0.415, I <sup>2</sup> =0%	P=0.290, I <sup>2</sup> =1081%	
Nervous system disorders	Headache	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Headache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Nervous system disorders	Dizziness		3.1% (0.4, 19.1)	11.1% (2.8, 35.2)	P=0.174, I <sup>2</sup> =0%	P=0.867, I <sup>2</sup> =0%							
Nervous system disorders	Dizziness	Mild	3.1% (0.4, 19.1)	11.1% (2.8, 35.2)	P=0.174, I <sup>2</sup> =0%	P=0.867, I <sup>2</sup> =0%	0.272 (0.023, 3.258)	0.299 (0.031, 2.888)	-0.078 (-0.235, 0.080)	P=0.551, I <sup>2</sup> =0%	P=0.535, I <sup>2</sup> =0%	P=0.707, I <sup>2</sup> =0%	
Nervous system disorders	Dizziness	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Dizziness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Nervous system disorders	Post-traumatic headache		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Post-traumatic headache	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Post-traumatic headache	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Post-traumatic headache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Migraine		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Nervous system disorders	Migraine	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Migraine	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Migraine	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Tremor		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Tremor	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Nervous system disorders	Tremor	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Nervous system disorders	Tremor	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications			9.4% (3.1, 25.4)	5.6% (0.8, 30.7)	P=0.068 , I <sup>2</sup> =0%	P=0.269 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications		Mild	6.3% (1.6, 21.8)	5.6% (0.8, 30.7)	P=0.140, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	1.059 (0.084, 13.329)	1.053 (0.108, 10.240) 0.965	0.003 (-0.129, 0.135)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications		Moderate	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029, 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Injury, poisoning and procedural complications	Head injury		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Head injury	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Head injury	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Injury, poisoning and procedural complications	Head injury	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal bite		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal bite	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Injury, poisoning and procedural complications	Animal bite	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal bite	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Injury, poisoning and procedural complications	Arthropod bite		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Arthropod bite	Mild	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Arthropod bite	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications	Arthropod bite	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Contusion		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Contusion	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications	Contusion	Moderate	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Contusion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ligament sprain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications	Ligament sprain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ligament sprain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ligament sprain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications	Post-traumatic pain		0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Post-traumatic pain	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications	Post-traumatic pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Post-traumatic pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Skin laceration		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications	Skin laceration	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Skin laceration	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Skin laceration	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Injury, poisoning and procedural complications	Ankle fracture		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ankle fracture	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ankle fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Injury, poisoning and procedural complications	Ankle fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns first degree		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns first degree	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications	Burns first degree	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns first degree	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications	Burns second degree		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns second degree	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns second degree	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications	Burns second degree	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Concussion		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Concussion	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Injury, poisoning and procedural complications	Concussion	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Concussion	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Face injury		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Injury, poisoning and procedural complications	Face injury	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Face injury	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Face injury	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications	Fall		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Fall	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications	Fall	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Fall	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Laceration		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications	Laceration	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Laceration	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Laceration	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Injury, poisoning and procedural complications	Meniscus injury		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Meniscus injury	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Meniscus injury	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications	Meniscus injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Muscle strain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Muscle strain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications	Muscle strain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Muscle strain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Injury, poisoning and procedural complications	Radius fracture		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Radius fracture	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Radius fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Injury, poisoning and procedural complications	Radius fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Wrist fracture		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Wrist fracture	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Injury, poisoning and procedural complications	Wrist fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Wrist fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Thermal burn		0%	5.6% (0.8, 30.7)	P=1.000 , I <sup>2</sup> =0%	P=0.269 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications	Thermal burn	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Thermal burn	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Thermal burn	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications	Upper limb fracture		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Upper limb fracture	Mild	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications	Upper limb fracture	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Upper limb fracture	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal scratch		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications	Animal scratch	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal scratch	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal scratch	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications	Eye injury		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Eye injury	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Eye injury	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Injury, poisoning and procedural complications	Eye injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Joint injury		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Joint injury	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Injury, poisoning and procedural complications	Joint injury	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Joint injury	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders			18.8% (8.7, 35.9)	0%	P=0.606 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Skin and subcutaneous tissue disorders		Mild	18.8% (8.7, 35.9)	0%	P=0.606, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.189 (0.054 - 0.325)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.571, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Skin and subcutaneous tissue disorders	Rash		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Skin and subcutaneous tissue disorders	Urticaria		6.3% (1.6, 21.8)	0%	P=0.051, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria	Mild	6.3% (1.6, 21.8)	0%	P=0.051, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.066 (-0.020 - 0.152)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Urticaria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Skin and subcutaneous tissue disorders	Urticaria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis allergic		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis allergic	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Skin and subcutaneous tissue disorders	Dermatitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Eczema		3.1% (0.4, 19.1)	0%	P=0.174, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Eczema	Mild	3.1% (0.4, 19.1)	0%	P=0.174, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.029 - 0.095)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Skin and subcutaneous tissue disorders	Eczema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Eczema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis contact		6.3% (1.6, 21.8)	0%	P=0.782, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis contact	Mild	6.3% (1.6, 21.8)	0%	P=0.782, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.063 (-0.021 - 0.147)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.687, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Skin and subcutaneous tissue disorders	Dermatitis contact	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis contact	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria papular		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Skin and subcutaneous tissue disorders	Urticaria papular	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria papular	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria papular	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash erythematous		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Skin and subcutaneous tissue disorders	Rash erythematous	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash erythematous	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash erythematous	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Skin and subcutaneous tissue disorders	Rash pruritic		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash pruritic	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash pruritic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash pruritic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Skin and subcutaneous tissue disorders	Cafe au lait spots		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Cafe au lait spots	Mild	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Cafe au lait spots	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Skin and subcutaneous tissue disorders	Cafe au lait spots	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Keratosis pilaris		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Keratosis pilaris	Mild	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Keratosis pilaris	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Skin and subcutaneous tissue disorders	Keratosis pilaris	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Petechiae		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Petechiae	Mild	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Skin and subcutaneous tissue disorders	Petechiae	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Petechiae	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Pityriasis alba		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Pityriasis alba	Mild	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Skin and subcutaneous tissue disorders	Pityriasis alba	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Pityriasis alba	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dyshidrotic eczema		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria chronic		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Skin and subcutaneous tissue disorders	Urticaria chronic	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria chronic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria chronic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Skin and subcutaneous tissue disorders	Dermatitis		3.1% (0.4, 19.1)	0%	P=0.174, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis	Mild	3.1% (0.4, 19.1)	0%	P=0.174, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.029 - 0.095)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Dermatitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Eye disorders			3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%							
Eye disorders		Mild	3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	0.557 (0.033, 9.364)	0.557 (0.031, 9.949) 0.691	-0.024 (-0.146 - 0.098)	P=0.352, I <sup>2</sup> =0%	P=0.361, I <sup>2</sup> =0%	P=0.311, I <sup>2</sup> =250%	
Eye disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Eye disorders	Refraction disorder		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Refraction disorder	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Refraction disorder	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Refraction disorder	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Strabismus		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Eye disorders	Strabismus	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Strabismus	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Strabismus	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Conjunctivitis allergic		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Eye disorders	Conjunctivitis allergic	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Conjunctivitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Conjunctivitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Myopia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Myopia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Eye disorders	Myopia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Myopia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Eye swelling		3.1% (0.4, 19.1)	0%	P=0.302 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Eye swelling	Mild	3.1% (0.4, 19.1)	0%	P=0.302 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Eye disorders	Eye swelling	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Papilloedema		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Papilloedema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Papilloedema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Eye disorders	Papilloedema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Astigmatism		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Astigmatism	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Astigmatism	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Astigmatism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Eye disorders	Eye haemorrhage		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye haemorrhage	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye haemorrhage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye haemorrhage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Eye disorders	Hypermetropia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Hypermetropia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Hypermetropia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Hypermetropia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Corneal epithelium defect		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Eye disorders	Corneal epithelium defect	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Corneal epithelium defect	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Corneal epithelium defect	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Eye pain		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Eye pain	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Eye disorders	Eye pain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Eye pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Vitreous opacities		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Vitreous opacities	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Eye disorders	Vitreous opacities	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Vitreous opacities	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Xerophthalmia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Xerophthalmia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Xerophthalmia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Eye disorders	Xerophthal mia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Vernal keratoconjun ctivitis		0%	5.6% (0.8, 30.7)	P=1.000 , I <sup>2</sup> =0%	P=0.193 , I <sup>2</sup> =0%							
Eye disorders	Vernal keratoconjun ctivitis	Mild	0%	5.6% (0.8, 30.7)	P=1.000 , I <sup>2</sup> =0%	P=0.193 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.054 (-0.158 - 0.051)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
Eye disorders	Vernal keratoconjun ctivitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Eye disorders	Vernal keratoconjunctivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders			6.3% (1.6, 21.8)	5.6% (0.8, 30.7)	P=0.782, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders		Mild	6.3% (1.6, 21.8)	5.6% (0.8, 30.7)	P=0.782, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	1.114 (0.097, 12.786)	1.108 (0.111, 11.018) 0.93	0.006 (-0.131, 0.143)	P=0.515, I <sup>2</sup> =0%	P=0.515, I <sup>2</sup> =0%	P=0.522, I <sup>2</sup> =0%	



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Musculoskeletal and connective tissue disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Pain in extremity		3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Musculoskeletal and connective tissue disorders	Pain in extremity	Mild	3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	0.500 (0.028, 8.952)	0.526 (0.037, 7.554) 0.637	-0.027 (-0.148, 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders	Pain in extremity	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Pain in extremity	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Musculoskeletal and connective tissue disorders	Arthralgia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthralgia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthralgia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Musculoskeletal and connective tissue disorders	Arthralgia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Musculoskeletal pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Musculoskeletal and connective tissue disorders	Neck pain		0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck pain	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.057 (-0.164 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders	Neck pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Musculoskeletal and connective tissue disorders	Neck pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthritis reactive		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthritis reactive	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Musculoskeletal and connective tissue disorders	Arthritis reactive	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthritis reactive	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Back pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Musculoskeletal and connective tissue disorders	Back pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Back pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Musculoskeletal and connective tissue disorders	Back pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck mass		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck mass	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Musculoskeletal and connective tissue disorders	Neck mass	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck mass	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Pain in jaw		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Musculoskeletal and connective tissue disorders	Pain in jaw	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Pain in jaw	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Pain in jaw	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Musculoskeletal and connective tissue disorders	Synovial cyst		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Synovial cyst	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Synovial cyst	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Musculoskeletal and connective tissue disorders	Synovial cyst	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Scoliosis		3.1% (0.4, 19.1)	0%	P=0.174, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Musculoskeletal and connective tissue disorders	Scoliosis	Mild	3.1% (0.4, 19.1)	0%	P=0.174, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.029 - 0.095)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders	Scoliosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Scoliosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Metabolism and nutrition disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Metabolism and nutrition disorders	Hypertriglyceridaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypertriglyceridaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypertriglyceridaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Metabolism and nutrition disorders	Hypertriglyceridaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypercholesterolaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypercholesterolaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypercholesterolaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Metabolism and nutrition disorders	Hypercholesterolaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Decreased appetite		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Decreased appetite	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Metabolism and nutrition disorders	Decreased appetite	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Decreased appetite	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperuricaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperuricaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Metabolism and nutrition disorders	Hyperuricaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperuricaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Polydipsia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Metabolism and nutrition disorders	Polydipsia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Polydipsia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Polydipsia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Calcium deficiency		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Metabolism and nutrition disorders	Calcium deficiency	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Calcium deficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Calcium deficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Metabolism and nutrition disorders	Hyperglycemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperglycemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperglycemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperglycemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Metabolism and nutrition disorders	Hyperlipidaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperlipidaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperlipidaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Metabolism and nutrition disorders	Hyperlipidaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders			9.4% (3.1, 25.4)	5.6% (0.8, 30.7)	P=0.068, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%							
Endocrine disorders		Mild	9.4% (3.1, 25.4)	5.6% (0.8, 30.7)	P=0.068, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	1.671 (0.170, 16.457)	1.671 (0.161, 17.365) 0.667	0.036 (-0.113, 0.186)	P=0.149, I <sup>2</sup> =5187%	P=0.155, I <sup>2</sup> =5057%	P=0.126, I <sup>2</sup> =5730%	
Endocrine disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Endocrine disorders	Secondary hypothyroidism		9.4% (3.1, 25.4)	0%	P=0.068, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Secondary hypothyroidism	Mild	9.4% (3.1, 25.4)	0%	P=0.068, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.090 (-0.010 - 0.189)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Secondary hypothyroidism	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Secondary hypothyroidism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Endocrine disorders	Hypothyroidism		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Hypothyroidism	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Hypothyroidism	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Hypothyroidism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Diabetes insipidus		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Endocrine disorders	Diabetes insipidus	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Endocrine disorders	Diabetes insipidus	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Endocrine disorders	Diabetes insipidus	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Endocrine disorders	Secondary adrenocortical insufficiency		3.1% (0.4, 19.1)	0%	P=0.302 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Endocrine disorders	Secondary adrenocortical insufficiency	Mild	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Secondary adrenocortical insufficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Secondary adrenocortical insufficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Adrenal insufficiency		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Adrenal insufficiency	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Endocrine disorders	Adrenal insufficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Adrenal insufficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Precocious puberty		0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%							
Endocrine disorders	Precocious puberty	Mild	0%	5.6% (0.8, 30.7)	P=1.000, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.054 (-0.158 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Endocrine disorders	Precocious puberty	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Precocious puberty	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Blood and lymphatic system disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Anaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Blood and lymphatic system disorders	Anaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Iron deficiency anaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Blood and lymphatic system disorders	Iron deficiency anaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Iron deficiency anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Iron deficiency anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Blood and lymphatic system disorders	Lymphadenopathy		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenopathy	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenopathy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenopathy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Blood and lymphatic system disorders	Neutropenia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Neutropenia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Neutropenia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Blood and lymphatic system disorders	Neutropenia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Granulocytopenia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Granulocytopenia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Granulocytopenia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Blood and lymphatic system disorders	Granulocytopenia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Blood and lymphatic system disorders	Lymphadenitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Hypochromic anaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Hypochromic anaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Blood and lymphatic system disorders	Hypochromic anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Hypochromic anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Thymus disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Blood and lymphatic system disorders	Thymus disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Thymus disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Thymus disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders			3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Immune system disorders		Mild	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Immune system disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Seasonal allergy		3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Immune system disorders	Seasonal allergy	Mild	3.1% (0.4, 19.1)	0%	P=0.302, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.030 (-0.029 - 0.089)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Immune system disorders	Seasonal allergy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Seasonal allergy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Hypersensitivity		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Hypersensitivity	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Immune system disorders	Hypersensitivity	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Hypersensitivity	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Allergy to animal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Allergy to animal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Allergy to animal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Immune system disorders	Allergy to animal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Food allergy		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Food allergy	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Food allergy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Immune system disorders	Food allergy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Reproductiv e system and breast disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Penile adhesion		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Penile adhesion	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Reproductive system and breast disorders	Penile adhesion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Penile adhesion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Gynaecomastia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Gynaecomastia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Reproductive system and breast disorders	Gynaecomastia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Gynaecomastia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Genital discomfort		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Reproductive system and breast disorders	Genital discomfort	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Genital discomfort	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Genital discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Balanoposthitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Reproductiv e system and breast disorders	Balanoposth itis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Balanoposth itis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Balanoposth itis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Reproductive system and breast disorders	Pelvic fluid collection		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Pelvic fluid collection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Pelvic fluid collection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Pelvic fluid collection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Reproductiv e system and breast disorders	Testicular appendage torsion		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Testicular appendage torsion	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Testicular appendage torsion	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Reproductiv e system and breast disorders	Testicular appendage torsion	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders			6.3% (1.6, 21.8)	0%	P=0.140 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders		Mild	6.3% (1.6, 21.8)	0%	P=0.140 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.060 (-0.023 - 0.142)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
Ear and labyrinth disorders		Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Ear and labyrinth disorders	Ear pain		6.3% (1.6, 21.8)	0%	P=0.140, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Ear pain	Mild	6.3% (1.6, 21.8)	0%	P=0.140, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.060 (-0.023 - 0.142)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Ear and labyrinth disorders	Ear pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Ear pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Ear and labyrinth disorders	Cerumen impaction		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Cerumen impaction	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Cerumen impaction	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Cerumen impaction	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Motion sickness		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Ear and labyrinth disorders	Motion sickness	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Motion sickness	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Motion sickness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Psychiatric disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Attention deficit/hyperactivity disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Attention deficit/hyperactivity disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Psychiatric disorders	Attention deficit/hyperactivity disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Attention deficit/hyperactivity disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Affect lability		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Affect lability	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Affect lability	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Psychiatric disorders	Affect lability	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Depressive symptom		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Depressive symptom	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Depressive symptom	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Psychiatric disorders	Depressive symptom	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Enuresis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Enuresis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Enuresis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Enuresis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Cardiac disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinoatrial block		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Cardiac disorders	Sinoatrial block	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinoatrial block	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinoatrial block	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinus tachycardia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Cardiac disorders	Sinus tachycardia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinus tachycardia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinus tachycardia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Tachycardia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Tachycardia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Cardiac disorders	Tachycardia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Tachycardia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Myocarditis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Myocarditis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Myocarditis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Cardiac disorders	Myocarditis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Wandering pacemaker		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Wandering pacemaker	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Wandering pacemaker	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Cardiac disorders	Wandering pacemaker	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Mild	3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	0.500 (0.028, 8.952)	0.526 (0.037, 7.554) 0.637	-0.027 (-0.148 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma		3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302 , I <sup>2</sup> =0%	P=0.269 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Mild	3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	0.500 (0.028, 8.952)	0.526 (0.037, 7.554) 0.637	-0.027 (-0.148, 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Renal and urinary disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Pollakiuria		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Renal and urinary disorders	Pollakiuria	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Pollakiuria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Pollakiuria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Polyuria		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Renal and urinary disorders	Polyuria	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Polyuria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Polyuria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Nocturia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Nocturia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Renal and urinary disorders	Nocturia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Renal and urinary disorders	Nocturia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Vascular disorders			6.3% (1.6, 21.8)	0%	P=0.140 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Vascular disorders		Mild	6.3% (1.6, 21.8)	0%	P=0.140 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.060 (-0.023 - 0.142)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Vascular disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Hypotension		6.3% (1.6, 21.8)	0%	P=0.140, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Hypotension	Mild	6.3% (1.6, 21.8)	0%	P=0.140, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.060 (-0.023 - 0.142)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Vascular disorders	Hypotension	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Vascular disorders	Hypotension	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Cyanosis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Cyanosis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Cyanosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Vascular disorders	Cyanosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Female													
Congenital, familial and genetic disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Buried penis syndrome		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Buried penis syndrome	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Congenital, familial and genetic disorders	Buried penis syndrome	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Buried penis syndrome	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Supernumerary teeth		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Supernumerary teeth	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Congenital, familial and genetic disorders	Supernumerary teeth	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Supernumerary teeth	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Hepatobiliary disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders	Hepatomegaly		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders	Hepatomegaly	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders	Hepatomegaly	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.19.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Female													
Hepatobiliary disorders	Hepatomegaly	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.													

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Any adverse event			91.9% (82.0, 96.6)	88.2% (72.5, 95.5)	P=0.020, I <sup>2</sup> =0%	P=0.041, I <sup>2</sup> =0%							P=0.636
Any adverse event		Mild	71.0% (58.6, 80.9)	64.7% (47.6, 78.7)	P=0.000, I <sup>2</sup> =0%	P=0.048, I <sup>2</sup> =70%	1.345 (0.502, 3.605)	1.083 (0.826, 1.419) 0.565	0.054 (-0.126, 0.233)	P=0.143, I <sup>2</sup> =5333%	P=0.392, I <sup>2</sup> =0%	P=0.270, I <sup>2</sup> =1779%	P=0.359
Any adverse event		Moderate	21.0% (12.6, 32.8)	23.5% (12.2, 40.5)	P=0.000, I <sup>2</sup> =0%	P=0.368, I <sup>2</sup> =0%	0.885 (0.315, 2.490)	0.915 (0.435, 1.927) 0.815	-0.020 (-0.190, 0.150)	P=0.108, I <sup>2</sup> =6122%	P=0.113, I <sup>2</sup> =6026%	P=0.138, I <sup>2</sup> =5448%	P=0.365

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Any adverse event		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.461
Infections and infestations			58.1% (45.5, 69.6)	64.7% (47.6, 78.7)	P=0.065, I <sup>2</sup> =70%	P=0.663, I <sup>2</sup> =0%							P=0.854
Infections and infestations		Mild	41.9% (30.4, 54.5)	50.0% (33.8, 66.2)	P=0.787, I <sup>2</sup> =0%	P=0.724, I <sup>2</sup> =0%	0.719 (0.310, 1.668)	0.837 (0.536, 1.307) 0.434	-0.082 (-0.290, 0.126)	P=0.903, I <sup>2</sup> =0%	P=0.928, I <sup>2</sup> =0%	P=0.899, I <sup>2</sup> =0%	P=0.448
Infections and infestations		Moderate	16.1% (8.9, 27.5)	14.7% (6.3, 30.8)	P=0.001, I <sup>2</sup> =0%	P=0.930, I <sup>2</sup> =0%	1.144 (0.360, 3.639)	1.121 (0.420, 2.993) 0.82	0.018 (-0.133, 0.169)	P=0.065, I <sup>2</sup> =705%	P=0.075, I <sup>2</sup> =683%	P=0.049, I <sup>2</sup> =742%	P=0.076



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.461
Infections and infestations	Upper respiratory tract infection		16.1% (8.9, 27.5)	35.3% (21.3, 52.4)	P=0.000, I <sup>2</sup> =86.7%	P=0.012, I <sup>2</sup> =83%							P=0.157
Infections and infestations	Upper respiratory tract infection	Mild	16.1% (8.9, 27.5)	26.5% (14.4, 43.5)	P=0.000, I <sup>2</sup> =86.7%	P=0.042, I <sup>2</sup> =74%	0.449 (0.143, 1.402)	0.587 (0.282, 1.223) 0.155	-0.110 (-0.271, 0.050)	P=0.319, I <sup>2</sup> =0%	P=0.218, I <sup>2</sup> =3424%	P=0.931, I <sup>2</sup> =0%	P=0.445
Infections and infestations	Upper respiratory tract infection	Moderate	0%	8.8% (2.9, 24.0)	P=1.000, I <sup>2</sup> =0%	P=0.296, I <sup>2</sup> =2%	NA (NA, NA)	NA (NA, NA) NA	-0.089 (-0.185, 0.007)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.371, I <sup>2</sup> =0%	P=0.889

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Upper respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Nasopharyngitis		11.3% (5.5, 21.8)	11.8% (4.5, 27.5)	P=0.005, I <sup>2</sup> =0%	P=0.552, I <sup>2</sup> =0%							P=0.306
Infections and infestations	Nasopharyngitis	Mild	9.7% (4.4, 19.9)	11.8% (4.5, 27.5)	P=0.010, I <sup>2</sup> =0%	P=0.552, I <sup>2</sup> =0%	0.823 (0.212, 3.202)	0.845 (0.262, 2.724) 0.778	-0.018 (-0.148, 0.111)	P=0.286, I <sup>2</sup> =122%	P=0.285, I <sup>2</sup> =125%	P=0.374, I <sup>2</sup> =0%	P=0.655

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Nasopharyngitis	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.284
Infections and infestations	Nasopharyngitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Pharyngitis		4.8% (1.6, 14.0)	20.6% (10.1, 37.3)	P=0.074, I <sup>2</sup> =0%	P=0.549, I <sup>2</sup> =0%							P=0.204
Infections and infestations	Pharyngitis	Mild	3.2% (0.8, 12.0)	20.6% (10.1, 37.3)	P=0.146, I <sup>2</sup> =0%	P=0.549, I <sup>2</sup> =0%	0.127 (0.024, 0.669)	0.161 (0.036, 0.716) 0.016	-0.172 (-0.315 - -0.030)	P=0.645, I <sup>2</sup> =0%	P=0.610, I <sup>2</sup> =0%	P=0.865, I <sup>2</sup> =0%	P=0.109

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Pharyngitis	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Infections and infestations	Pharyngitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Respiratory tract infection		3.2% (0.8, 12.0)	8.8% (2.9, 24.0)	P=0.146, I <sup>2</sup> =0%	P=0.854, I <sup>2</sup> =0%							P=0.182
Infections and infestations	Respiratory tract infection	Mild	1.6% (0.2, 10.6)	5.9% (1.5, 20.7)	P=0.307, I <sup>2</sup> =0%	P=0.728, I <sup>2</sup> =0%	0.270 (0.024, 3.031)	0.279 (0.027, 2.906) 0.286	-0.043 (-0.128 - 0.043)	P=0.559, I <sup>2</sup> =0%	P=0.561, I <sup>2</sup> =0%	P=0.507, I <sup>2</sup> =0%	P=0.224

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Respiratory tract infection	Moderate	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	0.556 (0.033, 9.369)	0.568 (0.037, 8.612) 0.683	-0.013 (-0.077, 0.052)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.720
Infections and infestations	Respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Bronchitis		4.8% (1.6, 14.0)	2.9% (0.4, 18.1)	P=0.798, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.929
Infections and infestations	Bronchitis	Mild	3.2% (0.8, 12.0)	0%	P=0.779, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.032 (-0.012, 0.076)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.709, I <sup>2</sup> =0%	P=0.970

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Bronchitis	Moderate	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	0.556 (0.033, 9.369)	0.568 (0.037, 8.612) 0.683	-0.013 (-0.077, 0.052)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.811
Infections and infestations	Bronchitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Infections and infestations	Tonsillitis		3.2% (0.8, 12.0)	2.9% (0.4, 18.1)	P=0.053, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.861
Infections and infestations	Tonsillitis	Mild	3.2% (0.8, 12.0)	0%	P=0.053, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.031 (-0.012, 0.074)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.511

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Tonsillitis	Moderate	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.749
Infections and infestations	Tonsillitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Gastroenteritis		0%	5.9% (1.5, 20.7)	P=1.000, I <sup>2</sup> =0%	P=0.157, I <sup>2</sup> =0%							P=0.415
Infections and infestations	Gastroenteritis	Mild	0%	5.9% (1.5, 20.7)	P=1.000, I <sup>2</sup> =0%	P=0.157, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.058 (-0.137 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.399
Infections and infestations	Gastroenteritis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.704

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Gastroenteritis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Rhinitis		3.2% (0.8, 12.0)	2.9% (0.4, 18.1)	P=0.146, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.956
Infections and infestations	Rhinitis	Mild	3.2% (0.8, 12.0)	2.9% (0.4, 18.1)	P=0.146, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	1.101 (0.102, 11.854)	1.101 (0.105, 11.584)	0.003 (-0.071, 0.077)	P=0.190, I <sup>2</sup> =4186%	P=0.194, I <sup>2</sup> =4076%	P=0.192, I <sup>2</sup> =4133%	P=0.956
Infections and infestations	Rhinitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Rhinitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Pharyngitis streptococcal		4.8% (1.6, 14.0)	0%	P=0.074, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.105
Infections and infestations	Pharyngitis streptococcal	Mild	3.2% (0.8, 12.0)	0%	P=0.146, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.011 - 0.077)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.225
Infections and infestations	Pharyngitis streptococcal	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.320

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Pharyngitis streptococcal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Pneumonia		3.2% (0.8, 12.0)	2.9% (0.4, 18.1)	P=0.779, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.406
Infections and infestations	Pneumonia	Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	0.500 (0.029, 8.706)	0.520 (0.035, 7.657) 0.634	-0.014 (-0.078 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.992
Infections and infestations	Pneumonia	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.320

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Pneumonia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Sinusitis		1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.869
Infections and infestations	Sinusitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.944
Infections and infestations	Sinusitis	Moderate	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	0.550 (0.036, 8.507)	0.550 (0.037, 8.287)	-0.013 (-0.080, 0.053)	P=0.311, I <sup>2</sup> =252%	P=0.317, I <sup>2</sup> =0%	P=0.276, I <sup>2</sup> =1583%	P=0.717

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Sinusitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Ear infection		4.8% (1.6, 14.0)	2.9% (0.4, 18.1)	P=0.074, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.939
Infections and infestations	Ear infection	Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	0.556 (0.033, 9.369)	0.568 (0.037, 8.612)	-0.013 (-0.077 - 0.052)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.978
Infections and infestations	Ear infection	Moderate	3.2% (0.8, 12.0)	0%	P=0.146, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.033 (-0.011 - 0.077)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.971

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Ear infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Viral infection		4.8% (1.6, 14.0)	0%	P=0.074, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.970
Infections and infestations	Viral infection	Mild	4.8% (1.6, 14.0)	0%	P=0.074, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.049 (-0.004 - 0.103)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.862
Infections and infestations	Viral infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Infections and infestations	Viral infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Respiratory tract infection viral		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.628
Infections and infestations	Respiratory tract infection viral	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.965
Infections and infestations	Respiratory tract infection viral	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Respiratory tract infection viral	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Gastroenteritis viral		4.8% (1.6, 14.0)	0%	P=0.074, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.258
Infections and infestations	Gastroenteritis viral	Mild	4.8% (1.6, 14.0)	0%	P=0.074, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.049 (-0.004 - 0.103)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.258
Infections and infestations	Gastroenteritis viral	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Gastroenteritis viral	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Conjunctivitis		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.878
Infections and infestations	Conjunctivitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.813
Infections and infestations	Conjunctivitis	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Infections and infestations	Conjunctivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Otitis media acute		3.2% (0.8, 12.0)	0%	P=0.779, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.163
Infections and infestations	Otitis media acute	Mild	3.2% (0.8, 12.0)	0%	P=0.779, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.032 (-0.012 - 0.076)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.709, I <sup>2</sup> =0%	P=0.286
Infections and infestations	Otitis media acute	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.704
Infections and infestations	Otitis media acute	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Varicella		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.698
Infections and infestations	Varicella	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.813
Infections and infestations	Varicella	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.747
Infections and infestations	Varicella	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Infections and infestations	Influenza		1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307 , I <sup>2</sup> =0%	P=0.322 , I <sup>2</sup> =0%							P=0.717

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Influenza	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.749
Infections and infestations	Influenza	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.976
Infections and infestations	Influenza	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Enteritis infectious		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.320

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Enteritis infectious	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Infections and infestations	Enteritis infectious	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.566
Infections and infestations	Enteritis infectious	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Enterobiasis		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.665

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Enterobiasis	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.665
Infections and infestations	Enterobiasis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Enterobiasis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Otitis media		1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.701

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Otitis media	Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	0.500 (0.029, 8.706)	0.520 (0.035, 7.657) 0.634	-0.014 (-0.078 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.701
Infections and infestations	Otitis media	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Otitis media	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Herpangina		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.516
Infections and infestations	Herpangina	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.516

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Herpangina	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Herpangina	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Periodontitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.516
Infections and infestations	Periodontitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.516

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Periodontitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Periodontitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Helminthic infection		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.435
Infections and infestations	Helminthic infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Helminthic infection	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.435



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Helminthic infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Hordeolum		1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.974
Infections and infestations	Hordeolum	Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	0.536 (0.032, 8.880)	0.536 (0.032, 9.117) 0.666	-0.013 (-0.078 - 0.051)	P=0.348, I <sup>2</sup> =0%	P=0.349, I <sup>2</sup> =0%	P=0.368, I <sup>2</sup> =0%	P=0.974
Infections and infestations	Hordeolum	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Hordeolum	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Pharyngoton sillitis		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.435
Infections and infestations	Pharyngoton sillitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.704
Infections and infestations	Pharyngoton sillitis	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Pharyngoton sillitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Infections and infestations	Viral upper respiratory tract infection		1.6% (0.2, 10.6)	0%	P=0.307 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.435
Infections and infestations	Viral upper respiratory tract infection	Mild	1.6% (0.2, 10.6)	0%	P=0.307 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.435
Infections and infestations	Viral upper respiratory tract infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Viral upper respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Pulpitis dental		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.562
Infections and infestations	Pulpitis dental	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.562
Infections and infestations	Pulpitis dental	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Pulpitis dental	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Urinary tract infection		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.981
Infections and infestations	Urinary tract infection	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.030 (-0.087 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.741
Infections and infestations	Urinary tract infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.704
Infections and infestations	Urinary tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Laryngitis		1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.440
Infections and infestations	Laryngitis	Mild	1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.440
Infections and infestations	Laryngitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Laryngitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Hand-foot-and-mouth disease		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.604
Infections and infestations	Hand-foot-and-mouth disease	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.604
Infections and infestations	Hand-foot-and-mouth disease	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Hand-foot-and-mouth disease	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Oral herpes		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.977

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Oral herpes	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.977
Infections and infestations	Oral herpes	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Oral herpes	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Atypical pneumonia		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Atypical pneumonia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Atypical pneumonia	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Infections and infestations	Atypical pneumonia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Conjunctivitis bacterial		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.749

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Conjunctivitis bacterial	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.749
Infections and infestations	Conjunctivitis bacterial	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Conjunctivitis bacterial	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Croup infectious		0%	3.6% (0.9, 13.4)	P=1.000, I <sup>2</sup> =0%	P=0.576, I <sup>2</sup> =0%							P=0.661
Infections and infestations	Croup infectious	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Croup infectious	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Croup infectious	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Cystitis		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703
Infections and infestations	Cystitis	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Cystitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Cystitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Laryngitis viral		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.749
Infections and infestations	Laryngitis viral	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.749
Infections and infestations	Laryngitis viral	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Laryngitis viral	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Otitis externa		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703
Infections and infestations	Otitis externa	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Otitis externa	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Otitis externa	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Rotavirus infection		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703
Infections and infestations	Rotavirus infection	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Infections and infestations	Rotavirus infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Rotavirus infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Vulvitis		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703
Infections and infestations	Vulvitis	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Infections and infestations	Vulvitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Vulvitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Appendicitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Infections and infestations	Appendicitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Appendicitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Appendicitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Eczema infected		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.747
Infections and infestations	Eczema infected	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.747
Infections and infestations	Eczema infected	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Infections and infestations	Eczema infected	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Infections and infestations	Infected bite		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.747

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Infected bite	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.747
Infections and infestations	Infected bite	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Infections and infestations	Infected bite	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Infections and infestations	Molluscum contagiosum		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.747
Infections and infestations	Molluscum contagiosum	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.747

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Molluscum contagiosum	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Infections and infestations	Molluscum contagiosum	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Infections and infestations	Tinea pedis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.747
Infections and infestations	Tinea pedis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.747

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Tinea pedis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Infections and infestations	Tinea pedis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Infections and infestations	Tooth abscess		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.747
Infections and infestations	Tooth abscess	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.747
Infections and infestations	Tooth abscess	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Tooth abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Abscess limb		1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.706
Infections and infestations	Abscess limb	Mild	1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706
Infections and infestations	Abscess limb	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Abscess limb	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Bacterial infection		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Infections and infestations	Bacterial infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Infections and infestations	Bacterial infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Bacterial infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Chronic sinusitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.745
Infections and infestations	Chronic sinusitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.745
Infections and infestations	Chronic sinusitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Infections and infestations	Chronic sinusitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Infections and infestations	Chronic tonsillitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.745

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Chronic tonsillitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Infections and infestations	Chronic tonsillitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Chronic tonsillitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Folliculitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Folliculitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Infections and infestations	Folliculitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Folliculitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Gastrointestinal bacterial infection		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Infections and infestations	Gastrointestinal bacterial infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Gastrointestinal bacterial infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Gastrointestinal bacterial infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Herpes virus infection		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Infections and infestations	Herpes virus infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Infections and infestations	Herpes virus infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Herpes virus infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Infectious mononucleosis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Infections and infestations	Infectious mononucleosis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Infections and infestations	Infectious mononucleosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Infectious mononucleosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Mumps		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Infections and infestations	Mumps	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Infections and infestations	Mumps	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Mumps	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Myringitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.745
Infections and infestations	Myringitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.745
Infections and infestations	Myringitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Infections and infestations	Myringitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Infections and infestations	Peritonsillar abscess		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.707

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Peritonsillar abscess	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Peritonsillar abscess	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Infections and infestations	Peritonsillar abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Sinobronchitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Sinobronchitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Infections and infestations	Sinobronchitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Sinobronchitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Subcutaneous abscess		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Infections and infestations	Subcutaneous abscess	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Subcutaneous abscess	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Infections and infestations	Subcutaneous abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Tonsillitis bacterial		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Infections and infestations	Tonsillitis bacterial	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Infections and infestations	Tonsillitis bacterial	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Tonsillitis bacterial	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Infections and infestations	Tracheitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Infections and infestations	Tracheitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Infections and infestations	Tracheitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Infections and infestations	Tracheitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations			24.2% (15.1, 36.3)	29.4% (16.6, 46.6)	P=0.000, I <sup>2</sup> =90.5%	P=0.001, I <sup>2</sup> =88%							P=0.495
Investigations		Mild	24.2% (15.1, 36.3)	29.4% (16.6, 46.6)	P=0.000, I <sup>2</sup> =90.5%	P=0.001, I <sup>2</sup> =88%	0.655 (0.219, 1.961)	0.794 (0.442, 1.425) 0.44	-0.061 (-0.223, 0.100)	P=0.752, I <sup>2</sup> =0%	P=0.921, I <sup>2</sup> =0%	P=0.455, I <sup>2</sup> =0%	P=0.495
Investigations		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Blood glucose increased		6.5% (2.4, 16.0)	17.6% (8.1, 34.1)	P=0.006, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%							P=0.454
Investigations	Blood glucose increased	Mild	6.5% (2.4, 16.0)	17.6% (8.1, 34.1)	P=0.006, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%	0.222 (0.048, 1.023)	0.347 (0.119, 1.014) 0.053	-0.117 (-0.248, 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.454
Investigations	Blood glucose increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Blood glucose increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Insulin-like growth factor increased		11.3% (5.5, 21.8)	2.9% (0.4, 18.1)	P=0.000, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.520
Investigations	Insulin-like growth factor increased	Mild	11.3% (5.5, 21.8)	2.9% (0.4, 18.1)	P=0.000, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	4.667 (0.507, 42.923)	3.640 (0.500, 26.501) 0.202	0.079 (-0.013 - 0.171)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.520
Investigations	Insulin-like growth factor increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Insulin-like growth factor increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Low density lipoprotein increased		1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.993
Investigations	Low density lipoprotein increased	Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	0.500 (0.029, 8.706)	0.520 (0.035, 7.657) 0.634	-0.014 (-0.078 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.993
Investigations	Low density lipoprotein increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Low density lipoprotein increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Blood alkaline phosphatase increased		1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.378
Investigations	Blood alkaline phosphatase increased	Mild	1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.378

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Blood alkaline phosphatase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Blood alkaline phosphatase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Eosinophil count increased		1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.832
Investigations	Eosinophil count increased	Mild	1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.832

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Eosinophil count increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Eosinophil count increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Alanine aminotransferase increased		3.2% (0.8, 12.0)	2.9% (0.4, 18.1)	P=0.053, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.806
Investigations	Alanine aminotransferase increased	Mild	3.2% (0.8, 12.0)	2.9% (0.4, 18.1)	P=0.053, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	1.073 (0.095, 12.098)	1.073 (0.093, 12.409) 0.955	0.002 (-0.070, 0.074)	P=0.216, I <sup>2</sup> =3470%	P=0.220, I <sup>2</sup> =3349%	P=0.206, I <sup>2</sup> =3739%	P=0.806
Investigations	Alanine aminotransferase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigation s	Alanine aminotransfe rase increased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Investigation s	Blood iron increased		3.2% (0.8, 12.0)	0%	P=0.053 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.139
Investigation s	Blood iron increased	Mild	3.2% (0.8, 12.0)	0%	P=0.053 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.031 (-0.012 - 0.074)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.139
Investigation s	Blood iron increased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Blood iron increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Blood phosphorus increased		3.2% (0.8, 12.0)	0%	P=0.053, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.727
Investigations	Blood phosphorus increased	Mild	3.2% (0.8, 12.0)	0%	P=0.053, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.031 (-0.012 - 0.074)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.727
Investigations	Blood phosphorus increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Blood phosphorus increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Blood uric acid increased		1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.642
Investigations	Blood uric acid increased	Mild	1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.642
Investigations	Blood uric acid increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Blood uric acid increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Cortisol decreased		1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.900
Investigations	Cortisol decreased	Mild	1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.900
Investigations	Cortisol decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Cortisol decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Aspartate aminotransferase increased		1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.721
Investigations	Aspartate aminotransferase increased	Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	0.536 (0.032, 8.880)	0.536 (0.032, 9.117) 0.666	-0.013 (-0.078, 0.051)	P=0.348, I <sup>2</sup> =0%	P=0.349, I <sup>2</sup> =0%	P=0.368, I <sup>2</sup> =0%	P=0.721
Investigations	Aspartate aminotransferase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Aspartate aminotransferase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Blood glucose abnormal		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.714
Investigations	Blood glucose abnormal	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.030 (-0.087 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.714
Investigations	Blood glucose abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Blood glucose abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Blood triglycerides increased		1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.674

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Blood triglycerides increased	Mild	1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.674
Investigations	Blood triglycerides increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Blood triglycerides increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Blood thyroid stimulating hormone increased		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.976
Investigations	Blood thyroid stimulating hormone increased	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.976
Investigations	Blood thyroid stimulating hormone increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Blood thyroid stimulating hormone increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	White blood cell count decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.562
Investigations	White blood cell count decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.562
Investigations	White blood cell count decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	White blood cell count decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Blood urea increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.569
Investigations	Blood urea increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.569
Investigations	Blood urea increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Blood urea increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Electrocardiogram T wave peaked		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.604
Investigations	Electrocardiogram T wave peaked	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.604
Investigations	Electrocardiogram T wave peaked	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Electrocardiogram T wave peaked	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Tri-iodothyronine free increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.977
Investigations	Tri-iodothyronine free increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.977
Investigations	Tri-iodothyronine free increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Tri-iodothyronine free increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Blood cortisol decreased		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703
Investigations	Blood cortisol decreased	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Investigations	Blood cortisol decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Blood cortisol decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Blood iron decreased		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.749

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Blood iron decreased	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.749
Investigations	Blood iron decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Blood iron decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Cortisol free urine decreased		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Cortisol free urine decreased	Mild	1.6% (0.2, 10.6)	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Investigations	Cortisol free urine decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Cortisol free urine decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Thyroxine decreased		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.749

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Thyroxine decreased	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.749
Investigations	Thyroxine decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Thyroxine decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Transaminases increased		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Transaminases increased	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Investigations	Transaminases increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Transaminases increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Blood cholesterol increased		1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.706
Investigations	Blood cholesterol increased	Mild	1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Blood cholesterol increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Blood cholesterol increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Electrocardiogram ST segment abnormal		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.741
Investigations	Electrocardiogram ST segment abnormal	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.030 (-0.087 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.741

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Electrocardiogram ST segment abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Electrocardiogram ST segment abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Thyroid function test abnormal		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.741
Investigations	Thyroid function test abnormal	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.030 (-0.087 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.741

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigation s	Thyroid function test abnormal	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Investigation s	Thyroid function test abnormal	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Investigation s	Thyroxine free decreased		1.6% (0.2, 10.6)	0%	P=0.175 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.706
Investigation s	Thyroxine free decreased	Mild	1.6% (0.2, 10.6)	0%	P=0.175 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.046)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.706

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Thyroxine free decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Thyroxine free decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Basophil count increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Investigations	Basophil count increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Basophil count increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Basophil count increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Blood lactate dehydrogenase increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Investigations	Blood lactate dehydrogenase increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Blood lactate dehydrogenase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Blood lactate dehydrogenase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Blood potassium increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Investigations	Blood potassium increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Blood potassium increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Blood potassium increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Blood pressure increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Investigations	Blood pressure increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Investigations	Blood pressure increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Blood pressure increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Electrocardiogram high voltage		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Investigations	Electrocardiogram high voltage	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Investigations	Electrocardiogram high voltage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Electrocardiogram high voltage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Haemoglobin decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Investigations	Haemoglobin decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Investigations	Haemoglobin decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Haemoglobin decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Hepatic enzyme abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Investigations	Hepatic enzyme abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Investigations	Hepatic enzyme abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Hepatic enzyme abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Hepatic enzyme increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Hepatic enzyme increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Investigations	Hepatic enzyme increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Hepatic enzyme increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Lipids increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Investigations	Lipids increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Lipids increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Lipids increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Liver function test abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Investigations	Liver function test abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Investigations	Liver function test abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Investigations	Liver function test abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Respiratory, thoracic and mediastinal disorders			25.8% (16.5, 38.1)	17.6% (8.1, 34.1)	P=0.789, I <sup>2</sup> =0%	P=0.518, I <sup>2</sup> =0%							P=0.877

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders		Mild	19.4% (11.3, 31.1)	17.6% (8.1, 34.1)	P=0.450, I <sup>2</sup> =0%	P=0.518, I <sup>2</sup> =0%	1.109 (0.373, 3.296)	1.087 (0.450, 2.623) 0.853	0.015 (-0.145, 0.176)	P=0.930, I <sup>2</sup> =0%	P=0.922, I <sup>2</sup> =0%	P=0.953, I <sup>2</sup> =0%	P=0.284
Respiratory, thoracic and mediastinal disorders		Moderate	6.5% (2.4, 16.0)	0%	P=0.038, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.066 (0.004, 0.128)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.257
Respiratory, thoracic and mediastinal disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Cough		16.1% (8.9, 27.5)	2.9% (0.4, 18.1)	P=0.499, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.271
Respiratory, thoracic and mediastinal disorders	Cough	Mild	14.5% (7.7, 25.6)	2.9% (0.4, 18.1)	P=0.318, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	5.752 (0.670, 49.404)	4.801 (0.656, 35.131) 0.122	0.114 (0.011, 0.217)	P=0.573, I <sup>2</sup> =0%	P=0.554, I <sup>2</sup> =0%	P=0.757, I <sup>2</sup> =0%	P=0.495



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Cough	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.213
Respiratory, thoracic and mediastinal disorders	Cough	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea		1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.713

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	0.536 (0.032, 8.880)	0.536 (0.032, 9.117) 0.666	-0.013 (-0.078, 0.051)	P=0.348, I <sup>2</sup> =0%	P=0.349, I <sup>2</sup> =0%	P=0.368, I <sup>2</sup> =0%	P=0.713
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic		1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.638
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	0.500 (0.029, 8.706)	0.520 (0.035, 7.657) 0.634	-0.014 (-0.078 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.638
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Respiratory, thoracic and mediastinal disorders	Asthma		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.701
Respiratory, thoracic and mediastinal disorders	Asthma	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.645

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Asthma	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.971
Respiratory, thoracic and mediastinal disorders	Asthma	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Respiratory disorder		1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.775
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	0.556 (0.033, 9.369)	0.568 (0.037, 8.612) 0.683	-0.013 (-0.077, 0.052)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.720
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.971

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Respiratory, thoracic and mediastinal disorders	Epistaxis		1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.566
Respiratory, thoracic and mediastinal disorders	Epistaxis	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.357

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Epistaxis	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Respiratory, thoracic and mediastinal disorders	Epistaxis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Respiratory, thoracic and mediastinal disorders	Nasal congestion		1.6% (0.2, 10.6)	5.9% (1.5, 20.7)	P=0.307, I <sup>2</sup> =0%	P=0.728, I <sup>2</sup> =0%							P=0.507



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Mild	0%	5.9% (1.5, 20.7)	P=1.000, I <sup>2</sup> =0%	P=0.728, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.059 (-0.138 - 0.020)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.734, I <sup>2</sup> =0%	P=0.314
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Wheezing		3.2% (0.8, 12.0)	2.9% (0.4, 18.1)	P=0.146, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.747
Respiratory, thoracic and mediastinal disorders	Wheezing	Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	0.556 (0.033, 9.369)	0.568 (0.037, 8.612) 0.683	-0.013 (-0.077, 0.052)	P=1.00, I <sup>2</sup> =0%	P=1.00, I <sup>2</sup> =0%	P=1.00, I <sup>2</sup> =0%	P=0.978

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Wheezing	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Respiratory, thoracic and mediastinal disorders	Wheezing	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Respiratory, thoracic and mediastinal disorders	Sinus congestion		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.869

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.607
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Allergic cough		3.2% (0.8, 12.0)	0%	P=0.779, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.525
Respiratory, thoracic and mediastinal disorders	Allergic cough	Mild	3.2% (0.8, 12.0)	0%	P=0.779, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.032 (-0.012 - 0.076)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.709, I <sup>2</sup> =0%	P=0.525
Respiratory, thoracic and mediastinal disorders	Allergic cough	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Allergic cough	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.976
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Laryngospasm		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain		1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.706
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Mild	1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Nasal obstruction		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Respiratory, thoracic and mediastinal disorders	Productive cough		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Respiratory, thoracic and mediastinal disorders	Productive cough	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Productive cough	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Respiratory, thoracic and mediastinal disorders	Productive cough	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders			30.6% (20.5, 43.1)	17.6% (8.1, 34.1)	P=0.849, I <sup>2</sup> =0%	P=0.518, I <sup>2</sup> =0%							P=0.153

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Gastrointestinal disorders		Mild	29.0% (19.1, 41.4)	17.6% (8.1, 34.1)	P=0.673, I <sup>2</sup> =0%	P=0.518, I <sup>2</sup> =0%	1.902 (0.671, 5.388)	1.635 (0.720, 3.714) 0.24	0.113 (-0.058 - 0.283)	P=0.745, I <sup>2</sup> =0%	P=0.709, I <sup>2</sup> =0%	P=0.834, I <sup>2</sup> =0%	P=0.249
Gastrointestinal disorders		Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.320
Gastrointestinal disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Diarrhoea		8.1% (3.4, 18.0)	8.8% (2.9, 24.0)	P=0.355, I <sup>2</sup> =0%	P=0.854, I <sup>2</sup> =0%							P=0.770

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Gastrointestinal disorders	Diarrhoea	Mild	8.1% (3.4, 18.0)	8.8% (2.9, 24.0)	P=0.355, I <sup>2</sup> =0%	P=0.854, I <sup>2</sup> =0%	0.897 (0.201, 4.013)	0.905 (0.228, 3.595) 0.887	-0.008 (-0.125, 0.109)	P=0.488, I <sup>2</sup> =0%	P=0.489, I <sup>2</sup> =0%	P=0.493, I <sup>2</sup> =0%	P=0.770
Gastrointestinal disorders	Diarrhoea	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Diarrhoea	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Vomiting		6.5% (2.4, 16.0)	2.9% (0.4, 18.1)	P=0.038, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.875

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Gastrointestinal disorders	Vomiting	Mild	6.5% (2.4, 16.0)	2.9% (0.4, 18.1)	P=0.038, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	2.424 (0.253, 23.246)	2.270 (0.271, 19.006) 0.449	0.037 (-0.045 - 0.119)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.808
Gastrointestinal disorders	Vomiting	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.704
Gastrointestinal disorders	Vomiting	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Nausea		3.2% (0.8, 12.0)	2.9% (0.4, 18.1)	P=0.146, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.851

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Gastrointestinal disorders	Nausea	Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	0.556 (0.033, 9.369)	0.568 (0.037, 8.612) 0.683	-0.013 (-0.077 - 0.052)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.408
Gastrointestinal disorders	Nausea	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.435
Gastrointestinal disorders	Nausea	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Abdominal pain		6.5% (2.4, 16.0)	2.9% (0.4, 18.1)	P=0.506, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.246

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Gastrointestinal disorders	Abdominal pain	Mild	4.8% (1.6, 14.0)	2.9% (0.4, 18.1)	P=0.798, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	1.710 (0.169, 17.345)	1.671 (0.179, 15.603) 0.652	0.020 (-0.058 - 0.097)	P=0.748, I <sup>2</sup> =0%	P=0.745, I <sup>2</sup> =0%	P=0.824, I <sup>2</sup> =0%	P=0.328
Gastrointestinal disorders	Abdominal pain	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Gastrointestinal disorders	Abdominal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Abdominal pain upper		3.2% (0.8, 12.0)	2.9% (0.4, 18.1)	P=0.779, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.578

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Gastrointestinal disorders	Abdominal pain upper	Mild	3.2% (0.8, 12.0)	2.9% (0.4, 18.1)	P=0.779, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	1.107 (0.096, 12.745)	1.104 (0.101, 12.086) 0.936	0.003 (-0.069, 0.075)	P=0.592, I <sup>2</sup> =0%	P=0.592, I <sup>2</sup> =0%	P=0.601, I <sup>2</sup> =0%	P=0.578
Gastrointestinal disorders	Abdominal pain upper	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Abdominal pain upper	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Dyspepsia		1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.595
Gastrointestinal disorders	Dyspepsia	Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	0.550 (0.036, 8.507)	0.550 (0.037, 8.287) 0.666	-0.013 (-0.080, 0.053)	P=0.311, I <sup>2</sup> =252%	P=0.317, I <sup>2</sup> =0%	P=0.276, I <sup>2</sup> =1583%	P=0.595

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Gastrointestinal disorders	Dyspepsia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Dyspepsia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Constipation		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.816
Gastrointestinal disorders	Constipation	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.877



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Gastrointesti nal disorders	Constipation	Moderate	1.6% (0.2, 10.6)	0%	P=0.307 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.703
Gastrointesti nal disorders	Constipation	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Gastrointesti nal disorders	Toothache		1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175 , I <sup>2</sup> =0%	P=0.160 , I <sup>2</sup> =0%							P=0.985
Gastrointesti nal disorders	Toothache	Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175 , I <sup>2</sup> =0%	P=0.160 , I <sup>2</sup> =0%	0.500 (0.029, 8.706)	0.520 (0.035, 7.657) 0.634	-0.014 (-0.078 - 0.050)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.985

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Gastrointesti nal disorders	Toothache	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Gastrointesti nal disorders	Toothache	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Gastrointesti nal disorders	Abdominal discomfort		1.6% (0.2, 10.6)	0%	P=0.307 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.973
Gastrointesti nal disorders	Abdominal discomfort	Mild	1.6% (0.2, 10.6)	0%	P=0.307 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.973
Gastrointesti nal disorders	Abdominal discomfort	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Gastrointestinal disorders	Abdominal discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Enteritis		1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.440
Gastrointestinal disorders	Enteritis	Mild	1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.440
Gastrointestinal disorders	Enteritis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Gastrointestinal disorders	Enteritis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Gastrointestinal disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.604
Gastrointestinal disorders	Gastrointestinal disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.604
Gastrointestinal disorders	Gastrointestinal disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Gastrointestinal disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Gastrointestinal disorders	Gastric disorder		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703
Gastrointestinal disorders	Gastric disorder	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Gastrointestinal disorders	Gastric disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Gastric disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Gastrointestinal disorders	Gastrointestinal motility disorder		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703
Gastrointestinal disorders	Gastrointestinal motility disorder	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Gastrointestinal disorders	Gastrointestinal motility disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Gastrointestinal motility disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Gastrointestinal disorders	Aphthous ulcer		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.704
Gastrointestinal disorders	Aphthous ulcer	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.704
Gastrointestinal disorders	Aphthous ulcer	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Aphthous ulcer	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Lip swelling		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Gastrointestinal disorders	Lip swelling	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Gastrointestinal disorders	Lip swelling	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Lip swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Abdominal distension		1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.706



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Gastrointesti nal disorders	Abdominal distension	Mild	1.6% (0.2, 10.6)	0%	P=0.175 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.046)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.706
Gastrointesti nal disorders	Abdominal distension	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Gastrointesti nal disorders	Abdominal distension	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Gastrointesti nal disorders	Noninfective gingivitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.707
Gastrointesti nal disorders	Noninfective gingivitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.707

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Gastrointestinal disorders	Noninfective gingivitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Gastrointestinal disorders	Noninfective gingivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
General disorders and administration site conditions			21.0% (12.6, 32.8)	14.7% (6.3, 30.8)	P=0.424, I <sup>2</sup> =0%	P=0.930, I <sup>2</sup> =0%							P=0.277

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administration site conditions		Mild	17.7% (10.1, 29.3)	8.8% (2.9, 24.0)	P=0.767, I <sup>2</sup> =0%	P=0.296, I <sup>2</sup> =2%	2.201 (0.573, 8.459)	1.998 (0.601, 6.645) 0.259	0.089 (-0.047, 0.224)	P=0.298, I <sup>2</sup> =749%	P=0.291, I <sup>2</sup> =1036%	P=0.347, I <sup>2</sup> =0%	P=0.195
General disorders and administration site conditions		Moderate	3.2% (0.8, 12.0)	5.9% (1.5, 20.7)	P=0.146, I <sup>2</sup> =0%	P=0.157, I <sup>2</sup> =0%	0.543 (0.071, 4.167)	0.568 (0.086, 3.740) 0.556	-0.025 (-0.114, 0.064)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.444

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administrati on site conditions		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
General disorders and administrati on site conditions	Pyrexia		19.4% (11.3, 31.1)	2.9% (0.4, 18.1)	P=0.579 , I <sup>2</sup> =0%	P=0.322 , I <sup>2</sup> =0%							P=0.064
General disorders and administrati on site conditions	Pyrexia	Mild	16.1% (8.9, 27.5)	2.9% (0.4, 18.1)	P=0.982 , I <sup>2</sup> =0%	P=0.322 , I <sup>2</sup> =0%	6.431 (0.777, 53.239)	5.550 (0.732, 42.095) 0.097	0.132 (0.025 - 0.240)	P=0.64 4, I <sup>2</sup> =0%	P=0.63 4, I <sup>2</sup> =0%	P=0.81 1, I <sup>2</sup> =0%	P=0.092

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administrati on site conditions	Pyrexia	Moderate	3.2% (0.8, 12.0)	0%	P=0.146 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.011 - 0.077)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.830
General disorders and administrati on site conditions	Pyrexia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administration site conditions	Injection site pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.516
General disorders and administration site conditions	Injection site pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.516

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administration site conditions	Injection site pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
General disorders and administration site conditions	Injection site pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
General disorders and administration site conditions	Injection site pruritus		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.794

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administrati on site conditions	Injection site pruritus	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.794
General disorders and administrati on site conditions	Injection site pruritus	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administration site conditions	Injection site pruritus	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
General disorders and administration site conditions	Fatigue		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.477

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administrati on site conditions	Fatigue	Mild	0%	2.9% (0.4, 18.1)	P=1.000 , I <sup>2</sup> =0%	P=0.322 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.477
General disorders and administrati on site conditions	Fatigue	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
General disorders and administrati on site conditions	Fatigue	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administrati on site conditions	Injection site swelling		0%	2.9% (0.4, 18.1)	P=1.000 , I <sup>2</sup> =0%	P=0.160 , I <sup>2</sup> =0%							P=0.981
General disorders and administrati on site conditions	Injection site swelling	Mild	0%	2.9% (0.4, 18.1)	P=1.000 , I <sup>2</sup> =0%	P=0.160 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.030 (-0.087 - 0.027)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.981

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administrati on site conditions	Injection site swelling	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
General disorders and administrati on site conditions	Injection site swelling	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administration site conditions	Injection site erythema		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.977
General disorders and administration site conditions	Injection site erythema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.977
General disorders and administration site conditions	Injection site erythema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administrati on site conditions	Injection site erythema	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
General disorders and administrati on site conditions	Injection site reaction		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.604

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administrati on site conditions	Injection site reaction	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.745
General disorders and administrati on site conditions	Injection site reaction	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.745

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administration site conditions	Injection site reaction	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
General disorders and administration site conditions	Face oedema		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.749
General disorders and administration site conditions	Face oedema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administration site conditions	Face oedema	Moderate	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.749
General disorders and administration site conditions	Face oedema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administrati on site conditions	Gait disturbance		1.6% (0.2, 10.6)	0%	P=0.307 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.703
General disorders and administrati on site conditions	Gait disturbance	Mild	1.6% (0.2, 10.6)	0%	P=0.307 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administrati on site conditions	Gait disturbance	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
General disorders and administrati on site conditions	Gait disturbance	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
General disorders and administrati on site conditions	Influenza like illness		0%	2.9% (0.4, 18.1)	P=1.000 , I <sup>2</sup> =0%	P=0.322 , I <sup>2</sup> =0%							P=0.749

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administration site conditions	Influenza like illness	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
General disorders and administration site conditions	Influenza like illness	Moderate	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.749

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administration site conditions	Influenza like illness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
General disorders and administration site conditions	Injection site atrophy		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administrati on site conditions	Injection site atrophy	Mild	1.6% (0.2, 10.6)	0%	P=0.307 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.703
General disorders and administrati on site conditions	Injection site atrophy	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
General disorders and administrati on site conditions	Injection site atrophy	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administrati on site conditions	Injection site urticaria		1.6% (0.2, 10.6)	0%	P=0.307 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.703
General disorders and administrati on site conditions	Injection site urticaria	Mild	1.6% (0.2, 10.6)	0%	P=0.307 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administrati on site conditions	Injection site urticaria	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
General disorders and administrati on site conditions	Injection site urticaria	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administrati on site conditions	Vaccination site pain		0%	2.9% (0.4, 18.1)	P=1.000 , I <sup>2</sup> =0%	P=0.322 , I <sup>2</sup> =0%							P=0.749
General disorders and administrati on site conditions	Vaccination site pain	Mild	0%	2.9% (0.4, 18.1)	P=1.000 , I <sup>2</sup> =0%	P=0.322 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.749
General disorders and administrati on site conditions	Vaccination site pain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administration site conditions	Vaccination site pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
General disorders and administration site conditions	Medical device discomfort		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.704

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administration site conditions	Medical device discomfort	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.704
General disorders and administration site conditions	Medical device discomfort	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administrati on site conditions	Medical device discomfort	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
General disorders and administrati on site conditions	Pain		0%	2.9% (0.4, 18.1)	P=1.000 , I <sup>2</sup> =0%	P=0.160 , I <sup>2</sup> =0%							P=0.741
General disorders and administrati on site conditions	Pain	Mild	0%	2.9% (0.4, 18.1)	P=1.000 , I <sup>2</sup> =0%	P=0.160 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.030 (-0.087 - 0.027)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.741

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administration site conditions	Pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
General disorders and administration site conditions	Pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administration site conditions	Injection site bruising		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
General disorders and administration site conditions	Injection site bruising	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administration site conditions	Injection site bruising	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
General disorders and administration site conditions	Injection site bruising	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
General disorders and administration site conditions	Injection site haemorrhage		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administration site conditions	Injection site haemorrhage	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
General disorders and administration site conditions	Injection site haemorrhage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administration site conditions	Injection site haemorrhage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
General disorders and administration site conditions	Peripheral swelling		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
General disorders and administration site conditions	Peripheral swelling	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
General disorders and administration site conditions	Peripheral swelling	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
General disorders and administration site conditions	Peripheral swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Nervous system disorders			8.1% (3.4, 18.0)	20.6% (10.1, 37.3)	P=0.313, I <sup>2</sup> =0%	P=0.779, I <sup>2</sup> =0%							P=0.400
Nervous system disorders		Mild	6.5% (2.4, 16.0)	17.6% (8.1, 34.1)	P=0.506, I <sup>2</sup> =0%	P=0.518, I <sup>2</sup> =0%	0.327 (0.086, 1.240)	0.367 (0.112, 1.210) 0.1	-0.112 (-0.255, 0.031)	P=0.369, I <sup>2</sup> =0%	P=0.376, I <sup>2</sup> =0%	P=0.393, I <sup>2</sup> =0%	P=0.438
Nervous system disorders		Moderate	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	0.556 (0.033, 9.369)	0.568 (0.037, 8.612) 0.683	-0.013 (-0.077, 0.052)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.849
Nervous system disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Nervous system disorders	Headache		6.5% (2.4, 16.0)	14.7% (6.3, 30.8)	P=0.038, I <sup>2</sup> =0%	P=0.930, I <sup>2</sup> =0%							P=0.594
Nervous system disorders	Headache	Mild	4.8% (1.6, 14.0)	11.8% (4.5, 27.5)	P=0.074, I <sup>2</sup> =0%	P=0.611, I <sup>2</sup> =0%	0.395 (0.084, 1.850)	0.419 (0.100, 1.754) 0.234	-0.069 (-0.191, 0.053)	P=0.223, I <sup>2</sup> =3252%	P=0.226, I <sup>2</sup> =3189%	P=0.269, I <sup>2</sup> =1800%	P=0.655
Nervous system disorders	Headache	Moderate	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	0.556 (0.033, 9.369)	0.568 (0.037, 8.612) 0.683	-0.013 (-0.077, 0.052)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.849
Nervous system disorders	Headache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Nervous system disorders	Dizziness		3.2% (0.8, 12.0)	5.9% (1.5, 20.7)	P=0.779, I <sup>2</sup> =0%	P=0.728, I <sup>2</sup> =0%							P=0.475
Nervous system disorders	Dizziness	Mild	3.2% (0.8, 12.0)	5.9% (1.5, 20.7)	P=0.779, I <sup>2</sup> =0%	P=0.728, I <sup>2</sup> =0%	0.528 (0.071, 3.933)	0.543 (0.080, 3.678)	-0.027 (-0.117 - 0.064)	P=0.959, I <sup>2</sup> =0%	P=0.964, I <sup>2</sup> =0%	P=0.866, I <sup>2</sup> =0%	P=0.475
Nervous system disorders	Dizziness	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Nervous system disorders	Dizziness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Nervous system disorders	Post-traumatic headache		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.435
Nervous system disorders	Post-traumatic headache	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.435
Nervous system disorders	Post-traumatic headache	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Nervous system disorders	Post-traumatic headache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Nervous system disorders	Migraine		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.749

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Nervous system disorders	Migraine	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.749
Nervous system disorders	Migraine	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Nervous system disorders	Migraine	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Nervous system disorders	Tremor		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Nervous system disorders	Tremor	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Nervous system disorders	Tremor	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Nervous system disorders	Tremor	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications			9.7% (4.4, 19.9)	5.9% (1.5, 20.7)	P=0.190, I <sup>2</sup> =27.1%	P=0.157, I <sup>2</sup> =0%							P=0.829



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications		Mild	6.5% (2.4, 16.0)	5.9% (1.5, 20.7)	P=0.506, I <sup>2</sup> =0%	P=0.157, I <sup>2</sup> =0%	1.130 (0.192, 6.636)	1.119 (0.217, 5.773) 0.893	0.007 (-0.092 - 0.106)	P=0.699, I <sup>2</sup> =0%	P=0.697, I <sup>2</sup> =0%	P=0.726, I <sup>2</sup> =0%	P=0.951
Injury, poisoning and procedural complications		Moderate	3.2% (0.8, 12.0)	0%	P=0.146, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.011 - 0.077)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.991
Injury, poisoning and procedural complications		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Head injury		3.2% (0.8, 12.0)	0%	P=0.779, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.286
Injury, poisoning and procedural complications	Head injury	Mild	3.2% (0.8, 12.0)	0%	P=0.779, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.032 (-0.012 - 0.076)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.709, I <sup>2</sup> =0%	P=0.286

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Head injury	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Head injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Post-traumatic pain		1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.978

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Post-traumatic pain	Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	0.556 (0.033, 9.369)	0.568 (0.037, 8.612) 0.683	-0.013 (-0.077, 0.052)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.978
Injury, poisoning and procedural complications	Post-traumatic pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Post-traumatic pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Contusion		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.973
Injury, poisoning and procedural complications	Contusion	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Injury, poisoning and procedural complications	Contusion	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Contusion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Ligament sprain		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.976
Injury, poisoning and procedural complications	Ligament sprain	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.976

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Ligament sprain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Ligament sprain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Animal bite		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.971
Injury, poisoning and procedural complications	Animal bite	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.971
Injury, poisoning and procedural complications	Animal bite	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Animal bite	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Arthropod bite		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.971
Injury, poisoning and procedural complications	Arthropod bite	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.971

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Arthropod bite	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Arthropod bite	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Skin laceration		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.604

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Skin laceration	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.745
Injury, poisoning and procedural complications	Skin laceration	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.745
Injury, poisoning and procedural complications	Skin laceration	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Ankle fracture		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703
Injury, poisoning and procedural complications	Ankle fracture	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Ankle fracture	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Injury, poisoning and procedural complications	Ankle fracture	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Concussion		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.749

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Concussion	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.749
Injury, poisoning and procedural complications	Concussion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Concussion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Thermal burn		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.749
Injury, poisoning and procedural complications	Thermal burn	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.749
Injury, poisoning and procedural complications	Thermal burn	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Thermal burn	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Upper limb fracture		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703
Injury, poisoning and procedural complications	Upper limb fracture	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Upper limb fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Upper limb fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Burns first degree		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.704
Injury, poisoning and procedural complications	Burns first degree	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.704
Injury, poisoning and procedural complications	Burns first degree	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Burns first degree	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Burns second degree		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Injury, poisoning and procedural complications	Burns second degree	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Burns second degree	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Injury, poisoning and procedural complications	Burns second degree	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Face injury		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Face injury	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Face injury	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Injury, poisoning and procedural complications	Face injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Fall		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Injury, poisoning and procedural complications	Fall	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Fall	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Fall	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Laceration		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Laceration	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Injury, poisoning and procedural complications	Laceration	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Laceration	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Meniscus injury		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.704
Injury, poisoning and procedural complications	Meniscus injury	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Meniscus injury	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.704

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Meniscus injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Muscle strain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Injury, poisoning and procedural complications	Muscle strain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Muscle strain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Injury, poisoning and procedural complications	Muscle strain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Radius fracture		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.747
Injury, poisoning and procedural complications	Radius fracture	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.747
Injury, poisoning and procedural complications	Radius fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Radius fracture	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Wrist fracture		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Injury, poisoning and procedural complications	Wrist fracture	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Wrist fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Wrist fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Animal scratch		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.707

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Animal scratch	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Injury, poisoning and procedural complications	Animal scratch	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Animal scratch	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Eye injury		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Injury, poisoning and procedural complications	Eye injury	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Eye injury	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Eye injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Joint injury		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Injury, poisoning and procedural complications	Joint injury	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Injury, poisoning and procedural complications	Joint injury	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Injury, poisoning and procedural complications	Joint injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Skin and subcutaneous tissue disorders			11.3% (5.5, 21.8)	5.9% (1.5, 20.7)	P=0.493, I <sup>2</sup> =0%	P=0.728, I <sup>2</sup> =0%							P=0.714
Skin and subcutaneous tissue disorders		Mild	9.7% (4.4, 19.9)	2.9% (0.4, 18.1)	P=0.711, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	3.436 (0.403, 29.283)	3.241 (0.414, 25.375) 0.263	0.067 (-0.027, 0.161)	P=0.320, I <sup>2</sup> =0%	P=0.308, I <sup>2</sup> =376%	P=0.401, I <sup>2</sup> =0%	P=0.943
Skin and subcutaneous tissue disorders		Moderate	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	0.556 (0.033, 9.369)	0.568 (0.037, 8.612) 0.683	-0.013 (-0.077, 0.052)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.673
Skin and subcutaneous tissue disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Skin and subcutaneous tissue disorders	Rash		1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.771
Skin and subcutaneous tissue disorders	Rash	Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	0.550 (0.036, 8.507)	0.550 (0.037, 8.287) 0.666	-0.013 (-0.080, 0.053)	P=0.311, I <sup>2</sup> =252%	P=0.317, I <sup>2</sup> =0%	P=0.276, I <sup>2</sup> =1583%	P=0.771
Skin and subcutaneous tissue disorders	Rash	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Skin and subcutaneous tissue disorders	Rash	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Skin and subcutaneous tissue disorders	Urticaria		1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.994
Skin and subcutaneous tissue disorders	Urticaria	Mild	1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.693
Skin and subcutaneous tissue disorders	Urticaria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.704

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Skin and subcutaneous tissue disorders	Urticaria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Skin and subcutaneous tissue disorders	Dermatitis allergic		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.999
Skin and subcutaneous tissue disorders	Dermatitis allergic	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.999

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Skin and subcutaneous tissue disorders	Dermatitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Skin and subcutaneous tissue disorders	Dermatitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Skin and subcutaneous tissue disorders	Eczema		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.866
Skin and subcutaneous tissue disorders	Eczema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.604

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Skin and subcutaneous tissue disorders	Eczema	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Skin and subcutaneous tissue disorders	Eczema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Skin and subcutaneous tissue disorders	Dermatitis contact		1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.977



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Skin and subcutaneous tissue disorders	Dermatitis contact	Mild	1.6% (0.2, 10.6)	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.977
Skin and subcutaneous tissue disorders	Dermatitis contact	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Skin and subcutaneous tissue disorders	Dermatitis contact	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Skin and subcutaneous tissue disorders	Urticaria papular		1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Skin and subcutaneous tissue disorders	Urticaria papular	Mild	1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.980
Skin and subcutaneous tissue disorders	Urticaria papular	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Skin and subcutaneous tissue disorders	Urticaria papular	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Skin and subcutaneous tissue disorders	Cafe au lait spots		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703
Skin and subcutaneous tissue disorders	Cafe au lait spots	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Skin and subcutaneous tissue disorders	Cafe au lait spots	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Skin and subcutaneous tissue disorders	Cafe au lait spots	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Skin and subcutaneous tissue disorders	Keratosis pilaris		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703
Skin and subcutaneous tissue disorders	Keratosis pilaris	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Skin and subcutaneous tissue disorders	Keratosis pilaris	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Skin and subcutaneous tissue disorders	Keratosis pilaris	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Skin and subcutaneous tissue disorders	Petechiae		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703
Skin and subcutaneous tissue disorders	Petechiae	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Skin and subcutaneous tissue disorders	Petechiae	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Skin and subcutaneous tissue disorders	Petechiae	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Skin and subcutaneous tissue disorders	Pityriasis alba		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703
Skin and subcutaneous tissue disorders	Pityriasis alba	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Skin and subcutaneous tissue disorders	Pityriasis alba	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Skin and subcutaneous tissue disorders	Pityriasis alba	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Skin and subcutaneous tissue disorders	Rash erythematous		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703
Skin and subcutaneous tissue disorders	Rash erythematous	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Skin and subcutaneous tissue disorders	Rash erythematous	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Skin and subcutaneous tissue disorders	Rash erythematous	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Skin and subcutaneous tissue disorders	Rash pruritic		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.749



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Skin and subcutaneous tissue disorders	Rash pruritic	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Skin and subcutaneous tissue disorders	Rash pruritic	Moderate	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.749
Skin and subcutaneous tissue disorders	Rash pruritic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Skin and subcutaneous tissue disorders	Dermatitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Skin and subcutaneous tissue disorders	Dermatitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Skin and subcutaneous tissue disorders	Dermatitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Skin and subcutaneous tissue disorders	Dermatitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Skin and subcutaneous tissue disorders	Dyshidrotic eczema		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Skin and subcutaneous tissue disorders	Urticaria chronic		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Skin and subcutaneous tissue disorders	Urticaria chronic	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Skin and subcutaneous tissue disorders	Urticaria chronic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Skin and subcutaneous tissue disorders	Urticaria chronic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders			8.1% (3.4, 18.0)	8.8% (2.9, 24.0)	P=0.988, I <sup>2</sup> =0%	P=0.854, I <sup>2</sup> =0%							P=0.520
Eye disorders		Mild	8.1% (3.4, 18.0)	8.8% (2.9, 24.0)	P=0.988, I <sup>2</sup> =0%	P=0.854, I <sup>2</sup> =0%	0.908 (0.203, 4.060)	0.916 (0.233, 3.605) 0.9	-0.007 (-0.124 - 0.110)	P=0.891, I <sup>2</sup> =0%	P=0.891, I <sup>2</sup> =0%	P=0.886, I <sup>2</sup> =0%	P=0.601
Eye disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Eye disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Refraction disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.859
Eye disorders	Refraction disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.859
Eye disorders	Refraction disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Refraction disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Eye disorders	Conjunctivitis allergic		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.976
Eye disorders	Conjunctivitis allergic	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.976
Eye disorders	Conjunctivitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Conjunctivitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Eye disorders	Eye swelling		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.976
Eye disorders	Eye swelling	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Eye disorders	Eye swelling	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Eye disorders	Eye swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Myopia		1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.974



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Eye disorders	Myopia	Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	0.536 (0.032, 8.880)	0.536 (0.032, 9.117) 0.666	-0.013 (-0.078 - 0.051)	P=0.348, I <sup>2</sup> =0%	P=0.349, I <sup>2</sup> =0%	P=0.368, I <sup>2</sup> =0%	P=0.974
Eye disorders	Myopia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Myopia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Strabismus		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.477

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Eye disorders	Strabismus	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.477
Eye disorders	Strabismus	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Strabismus	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Papilloedema		1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.993

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Eye disorders	Papilloedema	Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	0.500 (0.029, 8.706)	0.520 (0.035, 7.657) 0.634	-0.014 (-0.078 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.993
Eye disorders	Papilloedema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Papilloedema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Hypermetropia		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Eye disorders	Hypermetropia	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Eye disorders	Hypermetropia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Hypermetropia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Astigmatism		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Eye disorders	Astigmatism	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Eye disorders	Astigmatism	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Astigmatism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Eye haemorrhage		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Eye disorders	Eye haemorrhage	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Eye disorders	Eye haemorrhage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Eye disorders	Eye haemorrhage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Corneal epithelium defect		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Eye disorders	Corneal epithelium defect	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Eye disorders	Corneal epithelium defect	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Eye disorders	Corneal epithelium defect	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Eye pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Eye disorders	Eye pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Eye disorders	Eye pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Eye pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Eye disorders	Vernal keratoconjunctivitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Eye disorders	Vernal keratoconjunctivitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Eye disorders	Vernal keratoconjunctivitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Vernal keratoconjunctivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Vitreous opacities		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Eye disorders	Vitreous opacities	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Eye disorders	Vitreous opacities	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Vitreous opacities	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Xerophthalmia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Eye disorders	Xerophthalmia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Eye disorders	Xerophthalmia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Eye disorders	Xerophthalmia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Musculoskeletal and connective tissue disorders			11.3% (5.5, 21.8)	8.8% (2.9, 24.0)	P=0.493, I <sup>2</sup> =0%	P=0.080, I <sup>2</sup> =0%							P=0.994

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

					Lonapegsomatropin vs. Daily somatropin									
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )				
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction	
Baseline GH-stimulation strata: ≤ 5 ng/mL														
Musculoskeletal and connective tissue disorders		Mild	8.1% (3.4, 18.0)	8.8% (2.9, 24.0)	P=0.988, I <sup>2</sup> =0%	P=0.080, I <sup>2</sup> =0%	0.918 (0.205, 4.124)	0.925 (0.233, 3.679) 0.912	-0.007 (-0.123, 0.110)	P=0.337, I <sup>2</sup> =0%	P=0.342, I <sup>2</sup> =0%	P=0.281, I <sup>2</sup> =1394%	P=0.701	
Musculoskeletal and connective tissue disorders		Moderate	3.2% (0.8, 12.0)	0%	P=0.146, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.011, 0.077)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.565	
Musculoskeletal and connective tissue disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Musculoskel etal and connective tissue disorders	Pain in extremity		6.5% (2.4, 16.0)	2.9% (0.4, 18.1)	P=0.038 , I <sup>2</sup> =0%	P=0.322 , I <sup>2</sup> =0%							P=0.352
Musculoskel etal and connective tissue disorders	Pain in extremity	Mild	4.8% (1.6, 14.0)	2.9% (0.4, 18.1)	P=0.074 , I <sup>2</sup> =0%	P=0.322 , I <sup>2</sup> =0%	1.765 (0.172, 18.130)	1.703 (0.189, 15.350) 0.635	0.020 (-0.057 - 0.098)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.448
Musculoskel etal and connective tissue disorders	Pain in extremity	Moderate	1.6% (0.2, 10.6)	0%	P=0.307 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Musculoskeletal and connective tissue disorders	Pain in extremity	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Musculoskeletal and connective tissue disorders	Arthralgia		4.8% (1.6, 14.0)	2.9% (0.4, 18.1)	P=0.798, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.647

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

					Lonapegsomatropin vs. Daily somatropin									
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )				
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction	
Baseline GH-stimulation strata: ≤ 5 ng/mL														
Musculoskeletal and connective tissue disorders	Arthralgia	Mild	4.8% (1.6, 14.0)	2.9% (0.4, 18.1)	P=0.798, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	1.710 (0.169, 17.345)	1.671 (0.179, 15.603) 0.652	0.020 (-0.058 - 0.097)	P=0.748, I <sup>2</sup> =0%	P=0.745, I <sup>2</sup> =0%	P=0.824, I <sup>2</sup> =0%	P=0.647	
Musculoskeletal and connective tissue disorders	Arthralgia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980	
Musculoskeletal and connective tissue disorders	Arthralgia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Musculoskeletal and connective tissue disorders	Musculoskeletal pain		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.973
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Musculoskeletal and connective tissue disorders	Neck pain		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.477
Musculoskeletal and connective tissue disorders	Neck pain	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.477



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Musculoskeletal and connective tissue disorders	Neck pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Musculoskeletal and connective tissue disorders	Neck pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Musculoskeletal and connective tissue disorders	Back pain		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Musculoskeletal and connective tissue disorders	Back pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Musculoskeletal and connective tissue disorders	Back pain	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Musculoskeletal and connective tissue disorders	Back pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Musculoskeletal and connective tissue disorders	Neck mass		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703
Musculoskeletal and connective tissue disorders	Neck mass	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Musculoskeletal and connective tissue disorders	Neck mass	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Musculoskeletal and connective tissue disorders	Neck mass	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Musculoskeletal and connective tissue disorders	Pain in jaw		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Musculoskeletal and connective tissue disorders	Pain in jaw	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Musculoskeletal and connective tissue disorders	Pain in jaw	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Musculoskeletal and connective tissue disorders	Pain in jaw	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatotropin Mean (95%CI)	Daily somatotropin Mean (95%CI)	Lonapeg somatotropin	Daily somatotropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Musculoskeletal and connective tissue disorders	Synovial cyst		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.749
Musculoskeletal and connective tissue disorders	Synovial cyst	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.749
Musculoskeletal and connective tissue disorders	Synovial cyst	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Musculoskeletal and connective tissue disorders	Synovial cyst	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Musculoskeletal and connective tissue disorders	Arthritis reactive		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Musculoskeletal and connective tissue disorders	Arthritis reactive	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Musculoskeletal and connective tissue disorders	Arthritis reactive	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Musculoskeletal and connective tissue disorders	Arthritis reactive	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Musculoskeletal and connective tissue disorders	Scoliosis		1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.706
Musculoskeletal and connective tissue disorders	Scoliosis	Mild	1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706
Musculoskeletal and connective tissue disorders	Scoliosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Musculoskeletal and connective tissue disorders	Scoliosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Metabolism and nutrition disorders			6.5% (2.4, 16.0)	8.8% (2.9, 24.0)	P=0.145, I <sup>2</sup> =44.4%	P=0.012, I <sup>2</sup> =0%							P=0.666
Metabolism and nutrition disorders		Mild	6.5% (2.4, 16.0)	8.8% (2.9, 24.0)	P=0.145, I <sup>2</sup> =44.4%	P=0.012, I <sup>2</sup> =0%	0.663 (0.132, 3.328)	0.703 (0.178, 2.776) 0.616	-0.027 (-0.136, -0.083)	P=0.468, I <sup>2</sup> =0%	P=0.488, I <sup>2</sup> =0%	P=0.248, I <sup>2</sup> =2507%	P=0.666

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Metabolism and nutrition disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Metabolism and nutrition disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Metabolism and nutrition disorders	Hypertriglyceridaemia		1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.347
Metabolism and nutrition disorders	Hypertriglyceridaemia	Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	0.500 (0.029, 8.706)	0.520 (0.035, 7.657) 0.634	-0.014 (-0.078, 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.347

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Metabolism and nutrition disorders	Hypertriglyceridaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Metabolism and nutrition disorders	Hypertriglyceridaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Metabolism and nutrition disorders	Hypercholesterolaemia		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.518

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Metabolism and nutrition disorders	Hypercholesterolaemia	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.030 (-0.087 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.518
Metabolism and nutrition disorders	Hypercholesterolaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Metabolism and nutrition disorders	Hypercholesterolaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Metabolism and nutrition disorders	Hyperuricaemia		1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.701

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Metabolism and nutrition disorders	Hyperuricaemia	Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.175, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	0.500 (0.029, 8.706)	0.520 (0.035, 7.657) 0.634	-0.014 (-0.078 - 0.050)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.701
Metabolism and nutrition disorders	Hyperuricaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Metabolism and nutrition disorders	Hyperuricaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Metabolism and nutrition disorders	Decreased appetite		1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.674
Metabolism and nutrition disorders	Decreased appetite	Mild	1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.674
Metabolism and nutrition disorders	Decreased appetite	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Metabolism and nutrition disorders	Decreased appetite	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Metabolism and nutrition disorders	Polydipsia		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703
Metabolism and nutrition disorders	Polydipsia	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Metabolism and nutrition disorders	Polydipsia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Metabolism and nutrition disorders	Polydipsia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Metabolism and nutrition disorders	Hyperglycaemia		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.741
Metabolism and nutrition disorders	Hyperglycaemia	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.030 (-0.087 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.741
Metabolism and nutrition disorders	Hyperglycaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Metabolism and nutrition disorders	Hyperglycaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Metabolism and nutrition disorders	Calcium deficiency		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Metabolism and nutrition disorders	Calcium deficiency	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Metabolism and nutrition disorders	Calcium deficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Metabolism and nutrition disorders	Calcium deficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Metabolism and nutrition disorders	Hyperlipidaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Metabolism and nutrition disorders	Hyperlipidaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Metabolism and nutrition disorders	Hyperlipidaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Metabolism and nutrition disorders	Hyperlipidaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Endocrine disorders			9.7% (4.4, 19.9)	5.9% (1.5, 20.7)	P=0.190, I <sup>2</sup> =27.1%	P=0.157, I <sup>2</sup> =0%							P=0.269
Endocrine disorders		Mild	9.7% (4.4, 19.9)	5.9% (1.5, 20.7)	P=0.190, I <sup>2</sup> =27.1%	P=0.157, I <sup>2</sup> =0%	1.794 (0.332, 9.706)	1.687 (0.366, 7.777) 0.502	0.040 (-0.066, 0.146)	P=0.826, I <sup>2</sup> =0%	P=0.825, I <sup>2</sup> =0%	P=0.790, I <sup>2</sup> =0%	P=0.128

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Endocrine disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.607
Endocrine disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Endocrine disorders	Secondary hypothyroidism		6.5% (2.4, 16.0)	2.9% (0.4, 18.1)	P=0.038, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.520
Endocrine disorders	Secondary hypothyroidism	Mild	6.5% (2.4, 16.0)	2.9% (0.4, 18.1)	P=0.038, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	2.424 (0.253, 23.246)	2.270 (0.271, 19.006) 0.449	0.037 (-0.045, 0.119)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.378

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Endocrine disorders	Secondary hypothyroidism	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Endocrine disorders	Secondary hypothyroidism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Endocrine disorders	Hypothyroidism		1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.675
Endocrine disorders	Hypothyroidism	Mild	1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.675

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Endocrine disorders	Hypothyroidism	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Endocrine disorders	Hypothyroidism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Endocrine disorders	Secondary adrenocortical insufficiency		1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.978
Endocrine disorders	Secondary adrenocortical insufficiency	Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	0.556 (0.033, 9.369)	0.568 (0.037, 8.612) 0.683	-0.013 (-0.077, 0.052)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.978
Endocrine disorders	Secondary adrenocortical insufficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Endocrine disorders	Secondary adrenocortical insufficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Endocrine disorders	Diabetes insipidus		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.435
Endocrine disorders	Diabetes insipidus	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.435
Endocrine disorders	Diabetes insipidus	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Endocrine disorders	Diabetes insipidus	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Endocrine disorders	Adrenal insufficiency		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Endocrine disorders	Adrenal insufficiency	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Endocrine disorders	Adrenal insufficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Endocrine disorders	Adrenal insufficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Endocrine disorders	Precocious puberty		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Endocrine disorders	Precocious puberty	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Endocrine disorders	Precocious puberty	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Endocrine disorders	Precocious puberty	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Blood and lymphatic system disorders			8.1% (3.4, 18.0)	2.9% (0.4, 18.1)	P=0.313, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.883
Blood and lymphatic system disorders		Mild	4.8% (1.6, 14.0)	2.9% (0.4, 18.1)	P=0.798, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	1.647 (0.168, 16.174)	1.621 (0.179, 14.662) 0.667	0.019 (-0.060 - 0.097)	P=0.366, I <sup>2</sup> =0%	P=0.362, I <sup>2</sup> =0%	P=0.414, I <sup>2</sup> =0%	P=0.981
Blood and lymphatic system disorders		Moderate	3.2% (0.8, 12.0)	0%	P=0.146, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.011 - 0.077)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.817
Blood and lymphatic system disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Blood and lymphatic system disorders	Anaemia		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%							P=0.930
Blood and lymphatic system disorders	Anaemia	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.030 (-0.087 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.930
Blood and lymphatic system disorders	Anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Blood and lymphatic system disorders	Anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Blood and lymphatic system disorders	Iron deficiency anaemia		3.2% (0.8, 12.0)	0%	P=0.146, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.814
Blood and lymphatic system disorders	Iron deficiency anaemia	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.973
Blood and lymphatic system disorders	Iron deficiency anaemia	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Blood and lymphatic system disorders	Iron deficiency anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Blood and lymphatic system disorders	Lymphadenopathy		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.435
Blood and lymphatic system disorders	Lymphadenopathy	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.704

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Blood and lymphatic system disorders	Lymphadenopathy	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Blood and lymphatic system disorders	Lymphadenopathy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Blood and lymphatic system disorders	Neutropenia		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.973
Blood and lymphatic system disorders	Neutropenia	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.973

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Blood and lymphatic system disorders	Neutropenia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Blood and lymphatic system disorders	Neutropenia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Blood and lymphatic system disorders	Granulocytopenia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.604



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Blood and lymphatic system disorders	Granulocytopenia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.604
Blood and lymphatic system disorders	Granulocytopenia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Blood and lymphatic system disorders	Granulocytopenia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Blood and lymphatic system disorders	Lymphadenitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.604

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Blood and lymphatic system disorders	Lymphadenitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.604
Blood and lymphatic system disorders	Lymphadenitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Blood and lymphatic system disorders	Lymphadenitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Blood and lymphatic system disorders	Hypochromic anaemia		1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.706
Blood and lymphatic system disorders	Hypochromic anaemia	Mild	1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706
Blood and lymphatic system disorders	Hypochromic anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Blood and lymphatic system disorders	Hypochromic anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Blood and lymphatic system disorders	Thymus disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Blood and lymphatic system disorders	Thymus disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Blood and lymphatic system disorders	Thymus disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Blood and lymphatic system disorders	Thymus disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Immune system disorders			6.5% (2.4, 16.0)	0%	P=0.506, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.320
Immune system disorders		Mild	4.8% (1.6, 14.0)	0%	P=0.798, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.049 (-0.005 - 0.102)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.683, I <sup>2</sup> =0%	P=0.398
Immune system disorders		Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Immune system disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Immune system disorders	Seasonal allergy		3.2% (0.8, 12.0)	0%	P=0.146, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.716
Immune system disorders	Seasonal allergy	Mild	3.2% (0.8, 12.0)	0%	P=0.146, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.011 - 0.077)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.716
Immune system disorders	Seasonal allergy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Immune system disorders	Seasonal allergy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Immune system disorders	Hypersensitivity		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.284
Immune system disorders	Hypersensitivity	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.525
Immune system disorders	Hypersensitivity	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Immune system disorders	Hypersensitivity	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Immune system disorders	Allergy to animal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.607
Immune system disorders	Allergy to animal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.607
Immune system disorders	Allergy to animal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Immune system disorders	Allergy to animal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Immune system disorders	Food allergy		1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.706
Immune system disorders	Food allergy	Mild	1.6% (0.2, 10.6)	0%	P=0.175, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.046)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.706
Immune system disorders	Food allergy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Immune system disorders	Food allergy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Reproductive system and breast disorders			0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.388
Reproductive system and breast disorders		Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.388
Reproductive system and breast disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Reproductive system and breast disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Reproductive system and breast disorders	Penile adhesion		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.971
Reproductive system and breast disorders	Penile adhesion	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.971
Reproductive system and breast disorders	Penile adhesion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Reproductive system and breast disorders	Penile adhesion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Reproductive system and breast disorders	Gynaecomastia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.604
Reproductive system and breast disorders	Gynaecomastia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.604
Reproductive system and breast disorders	Gynaecomastia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Reproductive system and breast disorders	Gynaecomastia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Reproductive system and breast disorders	Genital discomfort		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.704
Reproductive system and breast disorders	Genital discomfort	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.704

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Reproductive system and breast disorders	Genital discomfort	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Reproductive system and breast disorders	Genital discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Reproductive system and breast disorders	Balanoposthitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Reproductive system and breast disorders	Balanoposthitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Reproductive system and breast disorders	Balanoposthitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Reproductive system and breast disorders	Balanoposthitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Reproductive system and breast disorders	Pelvic fluid collection		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Reproductive system and breast disorders	Pelvic fluid collection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Reproductive system and breast disorders	Pelvic fluid collection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Reproductive system and breast disorders	Pelvic fluid collection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Reproductive system and breast disorders	Testicular appendage torsion		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Reproductive system and breast disorders	Testicular appendage torsion	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Reproductive system and breast disorders	Testicular appendage torsion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Reproductive system and breast disorders	Testicular appendage torsion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Ear and labyrinth disorders			4.8% (1.6, 14.0)	0%	P=0.074, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.600

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Ear and labyrinth disorders		Mild	4.8% (1.6, 14.0)	0%	P=0.074, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.049 (-0.004 - 0.103)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.600
Ear and labyrinth disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Ear and labyrinth disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Ear and labyrinth disorders	Ear pain		4.8% (1.6, 14.0)	0%	P=0.074, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.710

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Ear and labyrinth disorders	Ear pain	Mild	4.8% (1.6, 14.0)	0%	P=0.074, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.049 (-0.004 - 0.103)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.710
Ear and labyrinth disorders	Ear pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Ear and labyrinth disorders	Ear pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Ear and labyrinth disorders	Cerumen impaction		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Ear and labyrinth disorders	Cerumen impaction	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.707
Ear and labyrinth disorders	Cerumen impaction	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Ear and labyrinth disorders	Cerumen impaction	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Ear and labyrinth disorders	Motion sickness		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.745
Ear and labyrinth disorders	Motion sickness	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.745

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Ear and labyrinth disorders	Motion sickness	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Ear and labyrinth disorders	Motion sickness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Psychiatric disorders			1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.471
Psychiatric disorders		Mild	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	0.556 (0.033, 9.369)	0.568 (0.037, 8.612)	-0.013 (-0.077 - 0.052)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.566

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Psychiatric disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Psychiatric disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Psychiatric disorders	Attention deficit/hyperactivity disorder		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.477
Psychiatric disorders	Attention deficit/hyperactivity disorder	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.477
Psychiatric disorders	Attention deficit/hyperactivity disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Psychiatric disorders	Attention deficit/hyper activity disorder	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Psychiatric disorders	Affect lability		1.6% (0.2, 10.6)	0%	P=0.307 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.703
Psychiatric disorders	Affect lability	Mild	1.6% (0.2, 10.6)	0%	P=0.307 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Psychiatric disorders	Affect lability	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Psychiatric disorders	Affect lability	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Psychiatric disorders	Depressive symptom		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Psychiatric disorders	Depressive symptom	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Psychiatric disorders	Depressive symptom	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Psychiatric disorders	Depressive symptom	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Psychiatric disorders	Enuresis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Psychiatric disorders	Enuresis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Psychiatric disorders	Enuresis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Psychiatric disorders	Enuresis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Cardiac disorders			1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.697
Cardiac disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.461
Cardiac disorders		Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Cardiac disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Cardiac disorders	Sinus tachycardia		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Cardiac disorders	Sinus tachycardia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Cardiac disorders	Sinus tachycardia	Moderate	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Cardiac disorders	Sinus tachycardia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Cardiac disorders	Sinoatrial block		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Cardiac disorders	Sinoatrial block	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Cardiac disorders	Sinoatrial block	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Cardiac disorders	Sinoatrial block	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Cardiac disorders	Tachycardia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747
Cardiac disorders	Tachycardia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.747

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Cardiac disorders	Tachycardia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Cardiac disorders	Tachycardia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Cardiac disorders	Myocarditis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Cardiac disorders	Myocarditis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Cardiac disorders	Myocarditis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Cardiac disorders	Myocarditis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Cardiac disorders	Wandering pacemaker		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Cardiac disorders	Wandering pacemaker	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Cardiac disorders	Wandering pacemaker	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Cardiac disorders	Wandering pacemaker	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.288

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Mild	0%	2.9% (0.4, 18.1)	P=1.000 , I <sup>2</sup> =0%	P=0.322 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.288
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma		0%	2.9% (0.4, 18.1)	P=1.000 , I <sup>2</sup> =0%	P=0.322 , I <sup>2</sup> =0%							P=0.357

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Mild	0%	2.9% (0.4, 18.1)	P=1.000 , I <sup>2</sup> =0%	P=0.322 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.357

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.747
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.747

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Renal and urinary disorders			1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.672
Renal and urinary disorders		Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.672
Renal and urinary disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Renal and urinary disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Renal and urinary disorders	Polyuria		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.703
Renal and urinary disorders	Polyuria	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.703
Renal and urinary disorders	Polyuria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Renal and urinary disorders	Polyuria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Renal and urinary disorders	Pollakiuria		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.747
Renal and urinary disorders	Pollakiuria	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.747
Renal and urinary disorders	Pollakiuria	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Renal and urinary disorders	Pollakiuria	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Renal and urinary disorders	Nocturia		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.707



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Renal and urinary disorders	Nocturia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707
Renal and urinary disorders	Nocturia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Renal and urinary disorders	Nocturia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Vascular disorders			1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.822

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Vascular disorders		Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.822
Vascular disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Vascular disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Vascular disorders	Hypotension		1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.973
Vascular disorders	Hypotension	Mild	1.6% (0.2, 10.6)	0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.973

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Vascular disorders	Hypotension	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Vascular disorders	Hypotension	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Vascular disorders	Cyanosis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Vascular disorders	Cyanosis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Vascular disorders	Cyanosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Vascular disorders	Cyanosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Congenital, familial and genetic disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.604
Congenital, familial and genetic disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.604

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Congenital, familial and genetic disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Congenital, familial and genetic disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Congenital, familial and genetic disorders	Buried penis syndrome		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Congenital, familial and genetic disorders	Buried penis syndrome	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Congenital, familial and genetic disorders	Buried penis syndrome	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Congenital, familial and genetic disorders	Buried penis syndrome	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.980
Congenital, familial and genetic disorders	Supernumerary teeth		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.745

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Congenital, familial and genetic disorders	Supernumerary teeth	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.745
Congenital, familial and genetic disorders	Supernumerary teeth	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Congenital, familial and genetic disorders	Supernumerary teeth	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Hepatobiliary disorders			0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.749

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Hepatobiliary disorders		Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.749
Hepatobiliary disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Hepatobiliary disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Hepatobiliary disorders	Hepatomegaly		0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%							P=0.749



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL													
Hepatobiliary disorders	Hepatomegaly	Mild	0%	2.9% (0.4, 18.1)	P=1.000, I <sup>2</sup> =0%	P=0.322, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.029 (-0.086 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.749
Hepatobiliary disorders	Hepatomegaly	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Hepatobiliary disorders	Hepatomegaly	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Any adverse event			85.3% (78.5, 90.2)	78.7% (68.0, 86.5)	P=0.000 , I <sup>2</sup> =91.6%	P=0.001 , I <sup>2</sup> =88%							
Any adverse event		Mild	68.5% (60.5, 75.6)	58.7% (47.3, 69.2)	P=0.000 , I <sup>2</sup> =94.7%	P=0.000 , I <sup>2</sup> =96%	1.799 (0.920, 3.515)	1.175 (0.967, 1.429) 0.105	0.103 (-0.016 - 0.221)	P=0.091, I <sup>2</sup> =649%	P=0.003, I <sup>2</sup> =883%	P=0.017, I <sup>2</sup> =823%	
Any adverse event		Moderate	14.7% (9.8, 21.5)	20.0% (12.4, 30.6)	P=0.056 , I <sup>2</sup> =71%	P=0.000 , I <sup>2</sup> =89%	0.663 (0.312, 1.409)	0.727 (0.408, 1.298) 0.282	-0.055 (-0.159 - 0.049)	P=0.113, I <sup>2</sup> =602%	P=0.141, I <sup>2</sup> =539%	P=0.019, I <sup>2</sup> =818%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Any adverse event		Severe	2.1% (0.7, 6.3)	0%	P=0.614, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.021 (-0.002 - 0.045)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.615, I <sup>2</sup> =0%	
Infections and infestations			55.9% (47.7, 63.9)	60.0% (48.6, 70.4)	P=0.017, I <sup>2</sup> =82%	P=0.345, I <sup>2</sup> =0%							
Infections and infestations		Mild	48.3% (40.2, 56.4)	45.3% (34.5, 56.6)	P=0.003, I <sup>2</sup> =88.3%	P=0.001, I <sup>2</sup> =90%	1.151 (0.639, 2.072)	1.070 (0.803, 1.427) 0.644	0.032 (-0.101 - 0.165)	P=0.361, I <sup>2</sup> =0%	P=0.303, I <sup>2</sup> =563%	P=0.365, I <sup>2</sup> =0%	
Infections and infestations		Moderate	5.6% (2.8, 10.8)	14.7% (8.3, 24.6)	P=0.104, I <sup>2</sup> =56.3%	P=0.001, I <sup>2</sup> =85%	0.321 (0.120, 0.854)	0.377 (0.162, 0.876) 0.023	-0.092 (-0.179 - -0.005)	P=0.276, I <sup>2</sup> =157%	P=0.338, I <sup>2</sup> =0%	P=0.001, I <sup>2</sup> =907%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations		Severe	2.1% (0.7, 6.3)	0%	P=0.614, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.021 (-0.002 - 0.045)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.615, I <sup>2</sup> =0%	
Infections and infestations	Upper respiratory tract infection		28.0% (21.2, 35.9)	30.7% (21.3, 41.9)	P=0.000, I <sup>2</sup> =95.3 %	P=0.000, I <sup>2</sup> =92%							
Infections and infestations	Upper respiratory tract infection	Mild	28.0% (21.2, 35.9)	28.0% (19.0, 39.2)	P=0.000, I <sup>2</sup> =95.3 %	P=0.000, I <sup>2</sup> =0%	1.024 (0.498, 2.107)	1.013 (0.687, 1.493) 0.948	0.004 (-0.105 - 0.112)	P=0.171, I <sup>2</sup> =466 %	P=0.173, I <sup>2</sup> =461 %	P=0.079, I <sup>2</sup> =675 %	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Upper respiratory tract infection	Moderate	0%	2.7% (0.7, 10.0)	P=1.000, I <sup>2</sup> =0%	P=0.924, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.063 - 0.010)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.805, I <sup>2</sup> =0%	
Infections and infestations	Upper respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Nasopharyngitis		4.9% (2.4, 9.9)	10.7% (5.4, 19.9)	P=0.190, I <sup>2</sup> =35.5%	P=0.342, I <sup>2</sup> =0%							
Infections and infestations	Nasopharyngitis	Mild	4.9% (2.4, 9.9)	8.0% (3.6, 16.7)	P=0.190, I <sup>2</sup> =35.5%	P=0.304, I <sup>2</sup> =0%	0.583 (0.187, 1.816)	0.607 (0.213, 1.730) 0.35	-0.032 (-0.102 - 0.039)	P=0.893, I <sup>2</sup> =0%	P=0.873, I <sup>2</sup> =0%	P=0.798, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Nasopharyngitis	Moderate	0%	2.7% (0.7, 10.0)	P=1.000, I <sup>2</sup> =0%	P=0.924, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.063 - 0.010)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.805, I <sup>2</sup> =0%	
Infections and infestations	Nasopharyngitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis		5.6% (2.8, 10.8)	6.7% (2.8, 15.0)	P=0.015, I <sup>2</sup> =74.4%	P=0.005, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis	Mild	5.6% (2.8, 10.8)	6.7% (2.8, 15.0)	P=0.015, I <sup>2</sup> =74.4%	P=0.005, I <sup>2</sup> =0%	0.806 (0.246, 2.642)	0.826 (0.289, 2.358) 0.721	-0.012 (-0.078 - 0.054)	P=0.619, I <sup>2</sup> =0%	P=0.628, I <sup>2</sup> =0%	P=0.360, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Pharyngitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection		7.0% (3.8, 12.5)	4.0% (1.3, 11.7)	P=0.872, I <sup>2</sup> =0%	P=0.633, I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection	Mild	6.3% (3.3, 11.7)	4.0% (1.3, 11.7)	P=0.847, I <sup>2</sup> =0%	P=0.633, I <sup>2</sup> =0%	1.617 (0.424, 6.167)	1.577 (0.440, 5.655) 0.484	0.023 (-0.037, 0.083)	P=0.753, I <sup>2</sup> =0%	P=0.750, I <sup>2</sup> =0%	P=0.819, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Respiratory tract infection	Moderate	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Bronchitis		6.3% (3.3, 11.7)	5.3% (2.0, 13.4)	P=0.016, I <sup>2</sup> =73.3%	P=0.891, I <sup>2</sup> =0%							
Infections and infestations	Bronchitis	Mild	4.9% (2.4, 9.9)	2.7% (0.7, 10.0)	P=0.056, I <sup>2</sup> =61.5%	P=0.109, I <sup>2</sup> =0%	1.935 (0.384, 9.745)	1.861 (0.402, 8.612) 0.427	0.023 (-0.027 - 0.073)	P=0.822, I <sup>2</sup> =0%	P=0.827, I <sup>2</sup> =0%	P=0.555, I <sup>2</sup> =0%	



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Bronchitis	Moderate	0.7% (0.1, 4.8)	2.7% (0.7, 10.0)	P=0.255, I <sup>2</sup> =0%	P=0.078, I <sup>2</sup> =0%	0.263 (0.024, 2.845)	0.263 (0.024, 2.838) 0.271	-0.020 (-0.059 - 0.019)	P=0.202, I <sup>2</sup> =386%	P=0.203, I <sup>2</sup> =381%	P=0.129, I <sup>2</sup> =566%	
Infections and infestations	Bronchitis	Severe	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Tonsillitis		3.5% (1.5, 8.1)	5.3% (2.0, 13.4)	P=0.192, I <sup>2</sup> =27.5%	P=0.022, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis	Mild	3.5% (1.5, 8.1)	5.3% (2.0, 13.4)	P=0.192, I <sup>2</sup> =27.5%	P=0.022, I <sup>2</sup> =0%	0.645 (0.165, 2.516)	0.664 (0.186, 2.366) 0.527	-0.018 (-0.076 - 0.041)	P=0.526, I <sup>2</sup> =0%	P=0.535, I <sup>2</sup> =0%	P=0.265, I <sup>2</sup> =195%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Tonsillitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis		2.8% (1.1, 7.2)	4.0% (1.3, 11.7)	P=0.257, I <sup>2</sup> =9.7%	P=0.633, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis	Mild	2.8% (1.1, 7.2)	2.7% (0.7, 10.0)	P=0.257, I <sup>2</sup> =9.7%	P=0.109, I <sup>2</sup> =0%	1.049 (0.189, 5.820)	1.048 (0.192, 5.718)	0.001 (-0.044 - 0.047)	P=0.158, I <sup>2</sup> =499%	P=0.160, I <sup>2</sup> =494%	P=0.135, I <sup>2</sup> =551%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Gastroenteritis	Moderate	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Gastroenteritis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rhinitis		2.8% (1.1, 7.2)	2.7% (0.7, 10.0)	P=0.921, I <sup>2</sup> =0%	P=0.078, I <sup>2</sup> =0%							
Infections and infestations	Rhinitis	Mild	2.8% (1.1, 7.2)	2.7% (0.7, 10.0)	P=0.921, I <sup>2</sup> =0%	P=0.078, I <sup>2</sup> =0%	1.043 (0.187, 5.818)	1.042 (0.197, 5.511) 0.962	0.001 (-0.044 - 0.047)	P=0.342, I <sup>2</sup> =0%	P=0.342, I <sup>2</sup> =0%	P=0.326, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Rhinitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rhinitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis streptococcal		0%	5.3% (2.0, 13.4)	P=1.000, I <sup>2</sup> =0%	P=0.012, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis streptococcal	Mild	0%	2.7% (0.7, 10.0)	P=1.000, I <sup>2</sup> =0%	P=0.078, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.027 (-0.063 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Pharyngitis streptococcal	Moderate	0%	2.7% (0.7, 10.0)	P=1.000, I <sup>2</sup> =0%	P=0.078, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.063 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pharyngitis streptococcal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pneumonia		0.7% (0.1, 4.8)	4.0% (1.3, 11.7)	P=0.255, I <sup>2</sup> =0%	P=0.477, I <sup>2</sup> =0%							
Infections and infestations	Pneumonia	Mild	0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.255, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	0.527 (0.032, 8.656)	0.533 (0.034, 8.302) 0.654	-0.006 (-0.035 - 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Pneumonia	Moderate	0%	2.7% (0.7, 10.0)	P=1.000, I <sup>2</sup> =0%	P=0.078, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.063 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pneumonia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinusitis		2.1% (0.7, 6.3)	2.7% (0.7, 10.0)	P=0.500, I <sup>2</sup> =0%	P=0.078, I <sup>2</sup> =0%							
Infections and infestations	Sinusitis	Mild	1.4% (0.4, 5.4)	2.7% (0.7, 10.0)	P=0.944, I <sup>2</sup> =0%	P=0.078, I <sup>2</sup> =0%	0.514 (0.071, 3.696)	0.521 (0.076, 3.588) 0.508	-0.013 (-0.054 - 0.028)	P=0.358, I <sup>2</sup> =0%	P=0.362, I <sup>2</sup> =0%	P=0.262, I <sup>2</sup> =2053%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Sinusitis	Moderate	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Sinusitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Ear infection		1.4% (0.4, 5.4)	0%	P=0.083, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Ear infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Ear infection	Moderate	1.4% (0.4, 5.4)	0%	P=0.083, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Ear infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral infection		2.1% (0.7, 6.3)	0%	P=0.033, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral infection	Mild	1.4% (0.4, 5.4)	0%	P=0.083, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Viral infection	Moderate	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Viral infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection viral		1.4% (0.4, 5.4)	2.7% (0.7, 10.0)	P=0.083, I <sup>2</sup> =0%	P=0.078, I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection viral	Mild	1.4% (0.4, 5.4)	2.7% (0.7, 10.0)	P=0.083, I <sup>2</sup> =0%	P=0.078, I <sup>2</sup> =0%	0.500 (0.067, 3.709)	0.515 (0.076, 3.501) 0.497	-0.013 (-0.054, 0.028)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Respiratory tract infection viral	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection viral	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis viral		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis viral	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Gastroenteritis viral	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis viral	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis		1.4% (0.4, 5.4)	1.3% (0.2, 8.9)	P=0.944, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis	Mild	1.4% (0.4, 5.4)	1.3% (0.2, 8.9)	P=0.944, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	1.055 (0.094, 11.877)	1.054 (0.096, 11.558)	0.001 (-0.032 - 0.033)	P=0.586, I <sup>2</sup> =0%	P=0.586, I <sup>2</sup> =0%	P=0.604, I <sup>2</sup> =0%	
Infections and infestations	Conjunctivitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Conjunctivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis media acute		0%	2.7% (0.7, 10.0)	P=1.000, I <sup>2</sup> =0%	P=0.924, I <sup>2</sup> =0%							
Infections and infestations	Otitis media acute	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Otitis media acute	Moderate	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Otitis media acute	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Varicella		2.1% (0.7, 6.3)	1.3% (0.2, 8.9)	P=0.500, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Infections and infestations	Varicella	Mild	1.4% (0.4, 5.4)	1.3% (0.2, 8.9)	P=0.944, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	1.055 (0.094, 11.877)	1.054 (0.096, 11.558) 0.965	0.001 (-0.032 - 0.033)	P=0.586, I <sup>2</sup> =0%	P=0.586, I <sup>2</sup> =0%	P=0.604, I <sup>2</sup> =0%	
Infections and infestations	Varicella	Moderate	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Varicella	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Influenza		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Influenza	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Influenza	Moderate	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Influenza	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Enteritis infectious		0%	2.7% (0.7, 10.0)	P=1.000, I <sup>2</sup> =0%	P=0.078, I <sup>2</sup> =0%							
Infections and infestations	Enteritis infectious	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Enteritis infectious	Moderate	0%	2.7% (0.7, 10.0)	P=1.000, I <sup>2</sup> =0%	P=0.078, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.063 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Enteritis infectious	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Enterobiasis		0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.222, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%							
Infections and infestations	Enterobiasis	Mild	0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.222, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	0.507 (0.031, 8.365)	0.515 (0.033, 7.984) 0.635	-0.007 (-0.036 - 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Enterobiasis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Enterobiasis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Otitis media		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis media	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Otitis media	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis media	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Herpangina		2.1% (0.7, 6.3)	0%	P=0.047, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Herpangina	Mild	2.1% (0.7, 6.3)	0%	P=0.047, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.021 (-0.002 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Herpangina	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Herpangina	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Periodontitis		2.1% (0.7, 6.3)	0%	P=0.047, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Periodontitis	Mild	2.1% (0.7, 6.3)	0%	P=0.047, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.021 (-0.002 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Periodontitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Periodontitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Helminthic infection		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Helminthic infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Helminthic infection	Moderate	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Helminthic infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hordeolum		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Hordeolum	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hordeolum	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hordeolum	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngotonsillitis		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Pharyngoton sillitis	Mild	0%	1.3% (0.2, 8.9)	P=1.000 , I <sup>2</sup> =0%	P=0.215 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Infections and infestations	Pharyngoton sillitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pharyngoton sillitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Viral upper respiratory tract infection		0%	1.3% (0.2, 8.9)	P=1.000 , I <sup>2</sup> =0%	P=0.215 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Viral upper respiratory tract infection	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Viral upper respiratory tract infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral upper respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pulpitis dental		1.4% (0.4, 5.4)	0%	P=0.944, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Pulpitis dental	Mild	1.4% (0.4, 5.4)	0%	P=0.944, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.033)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.718, I <sup>2</sup> =0%	
Infections and infestations	Pulpitis dental	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pulpitis dental	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Urinary tract infection		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%							
Infections and infestations	Urinary tract infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Urinary tract infection	Moderate	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Urinary tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Laryngitis		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Infections and infestations	Laryngitis	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Laryngitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Laryngitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hand-foot-and-mouth disease		1.4% (0.4, 5.4)	0%	P=0.106, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hand-foot-and-mouth disease	Mild	1.4% (0.4, 5.4)	0%	P=0.106, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Hand-foot-and-mouth disease	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hand-foot-and-mouth disease	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Oral herpes		0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.255, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Infections and infestations	Oral herpes	Mild	0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.255, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	0.527 (0.032, 8.656)	0.533 (0.034, 8.302) 0.654	-0.006 (-0.035, 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Oral herpes	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Oral herpes	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Atypical pneumonia		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Atypical pneumonia	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Atypical pneumonia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Atypical pneumonia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis bacterial		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis bacterial	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis bacterial	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis bacterial	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Croup infectious		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Croup infectious	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Croup infectious	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Croup infectious	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Cystitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Cystitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Cystitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Cystitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Laryngitis viral		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Laryngitis viral	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Laryngitis viral	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Laryngitis viral	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis externa		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis externa	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Otitis externa	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis externa	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rotavirus infection		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rotavirus infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Rotavirus infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Rotavirus infection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Vulvitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Vulvitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Vulvitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Vulvitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Appendicitis		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Appendicitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Appendicitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Appendicitis	Severe	0.7% (0.1, 4.8)	0%	P=0.222 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Infections and infestations	Eczema infected		0.7% (0.1, 4.8)	0%	P=0.222 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Eczema infected	Mild	0.7% (0.1, 4.8)	0%	P=0.222 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Infections and infestations	Eczema infected	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Eczema infected	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Infected bite		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Infected bite	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Infected bite	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Infected bite	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Molluscum contagiosum		0.7% (0.1, 4.8)	0%	P=0.222 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Molluscum contagiosum	Mild	0.7% (0.1, 4.8)	0%	P=0.222 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Infections and infestations	Molluscum contagiosum	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Molluscum contagiosum	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Tinea pedis		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tinea pedis	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Tinea pedis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tinea pedis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tooth abscess		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Tooth abscess	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Tooth abscess	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tooth abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Abscess limb		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Abscess limb	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Abscess limb	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Abscess limb	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Bacterial infection		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Bacterial infection	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Bacterial infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Bacterial infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Chronic sinusitis		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Chronic sinusitis	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Chronic sinusitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Chronic sinusitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Chronic tonsillitis		0.7% (0.1, 4.8)	0%	P=0.255 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Chronic tonsillitis	Mild	0.7% (0.1, 4.8)	0%	P=0.255 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Chronic tonsillitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Chronic tonsillitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Folliculitis		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Folliculitis	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Folliculitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Folliculitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastrointestinal bacterial infection		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastrointestinal bacterial infection	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Gastrointestinal bacterial infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Gastrointestinal bacterial infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Herpes virus infection		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Infections and infestations	Herpes virus infection	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Herpes virus infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Herpes virus infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Infectious mononucleosis		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Infections and infestations	Infectious mononucleosis	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Infectious mononucleosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Infectious mononucleosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Mumps		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Mumps	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Mumps	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Mumps	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Myringitis		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Myringitis	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Myringitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Myringitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Peritonsillar abscess		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Infections and infestations	Peritonsillar abscess	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Peritonsillar abscess	Moderate	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Peritonsillar abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Sinobronchitis		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Infections and infestations	Sinobronchitis	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Sinobronchitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinobronchitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Subcutaneous abscess		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Subcutaneous abscess	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Subcutaneous abscess	Moderate	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Subcutaneous abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis bacterial		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Tonsillitis bacterial	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis bacterial	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis bacterial	Severe	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Tracheitis		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Infections and infestations	Tracheitis	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Tracheitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tracheitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations			30.1% (23.1, 38.1)	29.3% (20.2, 40.6)	P=0.000, I <sup>2</sup> =95.9%	P=0.000, I <sup>2</sup> =91%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations		Mild	30.1% (23.1, 38.1)	29.3% (20.2, 40.6)	P=0.000, I <sup>2</sup> =95.9%	P=0.000, I <sup>2</sup> =91%	1.076 (0.529, 2.188)	1.039 (0.716, 1.508) 0.84	0.011 (-0.099, 0.121)	P=0.366, I <sup>2</sup> =0%	P=0.353, I <sup>2</sup> =0%	P=0.396, I <sup>2</sup> =0%	
Investigations		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood glucose increased		9.1% (5.4, 15.0)	16.0% (9.3, 26.1)	P=0.000, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%							
Investigations	Blood glucose increased	Mild	9.1% (5.4, 15.0)	16.0% (9.3, 26.1)	P=0.000, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%	0.489 (0.198, 1.207)	0.578 (0.291, 1.145) 0.116	-0.067 (-0.157, 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Blood glucose increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood glucose increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Insulin-like growth factor increased		16.8% (11.5, 23.8)	2.7% (0.7, 10.0)	P=0.000, I <sup>2</sup> =91.5%	P=0.109, I <sup>2</sup> =0%							
Investigations	Insulin-like growth factor increased	Mild	16.8% (11.5, 23.8)	2.7% (0.7, 10.0)	P=0.000, I <sup>2</sup> =91.5%	P=0.109, I <sup>2</sup> =0%	8.624 (1.911, 38.921)	6.388 (1.582, 25.790) 0.009	0.143 (0.073 - 0.212)	P=0.448, I <sup>2</sup> =0%	P=0.552, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =9472%	



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Insulin-like growth factor increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Insulin-like growth factor increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Low density lipoprotein increased		2.1% (0.7, 6.3)	4.0% (1.3, 11.7)	P=0.047, I <sup>2</sup> =0%	P=0.049, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Low density lipoprotein increased	Mild	2.1% (0.7, 6.3)	4.0% (1.3, 11.7)	P=0.047, I <sup>2</sup> =0%	P=0.049, I <sup>2</sup> =0%	0.514 (0.099, 2.672)	0.533 (0.113, 2.522) 0.428	-0.019 (-0.068, 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Low density lipoprotein increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Low density lipoprotein increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood alkaline phosphatase increased		1.4% (0.4, 5.4)	5.3% (2.0, 13.4)	P=0.106, I <sup>2</sup> =0%	P=0.022, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Blood alkaline phosphatase increased	Mild	1.4% (0.4, 5.4)	5.3% (2.0, 13.4)	P=0.106, I <sup>2</sup> =0%	P=0.022, I <sup>2</sup> =0%	0.247 (0.043, 1.410)	0.267 (0.051, 1.393) 0.117	-0.039 (-0.093, 0.015)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood alkaline phosphatase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood alkaline phosphatase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Investigation s	Eosinophil count increased		2.8% (1.1, 7.2)	1.3% (0.2, 8.9)	P=0.921, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Investigation s	Eosinophil count increased	Mild	2.8% (1.1, 7.2)	1.3% (0.2, 8.9)	P=0.921, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	2.139 (0.234, 19.572)	2.109 (0.238, 18.695) 0.503	0.015 (-0.023 - 0.052)	P=0.564, I <sup>2</sup> =0%	P=0.562, I <sup>2</sup> =0%	P=0.622, I <sup>2</sup> =0%	
Investigation s	Eosinophil count increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigation s	Eosinophil count increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigation s	Alanine aminotransf erase increased		0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.255, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Alanine aminotransferase increased	Mild	0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.255, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	0.527 (0.032, 8.656)	0.533 (0.034, 8.302) 0.654	-0.006 (-0.035 - 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Alanine aminotransferase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Alanine aminotransferase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron increased		0%	4.0% (1.3, 11.7)	P=1.000, I <sup>2</sup> =0%	P=0.633, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Blood iron increased	Mild	0%	4.0% (1.3, 11.7)	P=1.000, I <sup>2</sup> =0%	P=0.633, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.040 (-0.084 - 0.004)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.684, I <sup>2</sup> =0%	
Investigations	Blood iron increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood phosphorus increased		1.4% (0.4, 5.4)	1.3% (0.2, 8.9)	P=0.106, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Blood phosphorus increased	Mild	1.4% (0.4, 5.4)	1.3% (0.2, 8.9)	P=0.106, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	1.068 (0.094, 12.158)	1.067 (0.100, 11.406) 0.957	0.001 (-0.031 - 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood phosphorus increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood phosphorus increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood uric acid increased		1.4% (0.4, 5.4)	2.7% (0.7, 10.0)	P=0.106, I <sup>2</sup> =0%	P=0.109, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Blood uric acid increased	Mild	1.4% (0.4, 5.4)	2.7% (0.7, 10.0)	P=0.106, I <sup>2</sup> =0%	P=0.109, I <sup>2</sup> =0%	0.521 (0.071, 3.842)	0.533 (0.078, 3.645) 0.522	-0.012 (-0.053, 0.029)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood uric acid increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood uric acid increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol decreased		1.4% (0.4, 5.4)	1.3% (0.2, 8.9)	P=0.106, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Investigations	Cortisol decreased	Mild	1.4% (0.4, 5.4)	1.3% (0.2, 8.9)	P=0.106, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	1.068 (0.094, 12.158)	1.067 (0.100, 11.406) 0.957	0.001 (-0.031, 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Investigation s	Cortisol decreased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Cortisol decreased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Aspartate aminotransfe rase increased		0.7% (0.1, 4.8)	0%	P=0.255 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Aspartate aminotransfe rase increased	Mild	0.7% (0.1, 4.8)	0%	P=0.255 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Aspartate aminotransferase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Aspartate aminotransferase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood glucose abnormal		0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.255, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Investigations	Blood glucose abnormal	Mild	0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.255, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	0.527 (0.032, 8.656)	0.533 (0.034, 8.302) 0.654	-0.006 (-0.035, 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Blood glucose abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood glucose abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood triglycerides increased		0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.255, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Investigations	Blood triglycerides increased	Mild	0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.255, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	0.527 (0.032, 8.656)	0.533 (0.034, 8.302)	-0.006 (-0.035 - 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood triglycerides increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Blood triglycerides increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood thyroid stimulating hormone increased		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood thyroid stimulating hormone increased	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Blood thyroid stimulating hormone increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood thyroid stimulating hormone increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	White blood cell count decreased		1.4% (0.4, 5.4)	0%	P=0.944, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	White blood cell count decreased	Mild	1.4% (0.4, 5.4)	0%	P=0.944, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.033)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.718, I <sup>2</sup> =0%	
Investigations	White blood cell count decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	White blood cell count decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood urea increased		0%	2.7% (0.7, 10.0)	P=1.000, I <sup>2</sup> =0%	P=0.109, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Blood urea increased	Mild	0%	2.7% (0.7, 10.0)	P=1.000, I <sup>2</sup> =0%	P=0.109, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.063 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood urea increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood urea increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram T wave peaked		1.4% (0.4, 5.4)	0%	P=0.106, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Electrocardiogram T wave peaked	Mild	1.4% (0.4, 5.4)	0%	P=0.106, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Electrocardiogram T wave peaked	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram T wave peaked	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Tri-iodothyronine free increased		0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.255, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Tri-iodothyronine free increased	Mild	0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.255, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	0.527 (0.032, 8.656)	0.533 (0.034, 8.302) 0.654	-0.006 (-0.035 - 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Tri-iodothyronine free increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Tri-iodothyronine free increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cortisol decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cortisol decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Blood cortisol decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cortisol decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Blood iron decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol free urine decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol free urine decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol free urine decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Cortisol free urine decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Transaminases increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Transaminases increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Transaminases increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Transaminases increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Blood cholesterol increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram ST segment abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Electrocardiogram ST segment abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram ST segment abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram ST segment abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroid function test abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Thyroid function test abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroid function test abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroid function test abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine free decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Thyroxine free decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine free decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine free decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Basophil count increased		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Basophil count increased	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Basophil count increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Basophil count increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood lactate dehydrogenase increased		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Blood lactate dehydrogenase increased	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood lactate dehydrogenase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood lactate dehydrogenase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood potassium increased		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Blood potassium increased	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood potassium increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood potassium increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood pressure increased		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Investigation s	Blood pressure increased	Mild	0%	1.3% (0.2, 8.9)	P=1.000 , I <sup>2</sup> =0%	P=0.260 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Investigation s	Blood pressure increased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood pressure increased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Electrocardi ogram high voltage		0.7% (0.1, 4.8)	0%	P=0.255 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Electrocardi ogram high voltage	Mild	0.7% (0.1, 4.8)	0%	P=0.255 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Electrocardiogram high voltage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram high voltage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Haemoglobin decreased		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Investigations	Haemoglobin decreased	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Haemoglobin decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Haemoglobin decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme abnormal		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme abnormal	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Hepatic enzyme abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme increased		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme increased	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Hepatic enzyme increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Hepatic enzyme increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Lipids increased		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Investigations	Lipids increased	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Lipids increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Lipids increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Liver function test abnormal		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Investigations	Liver function test abnormal	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Liver function test abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Investigations	Liver function test abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders			30.8% (23.8, 38.8)	20.0% (12.4, 30.6)	P=0.153, I <sup>2</sup> =50.2%	P=0.243, I <sup>2</sup> =24%							
Respiratory, thoracic and mediastinal disorders		Mild	28.7% (21.9, 36.6)	14.7% (8.3, 24.6)	P=0.040, I <sup>2</sup> =75.4%	P=0.155, I <sup>2</sup> =46%	2.415 (1.145, 5.095)	1.966 (1.081, 3.573) 0.027	0.141 (0.034 - 0.249)	P=0.801, I <sup>2</sup> =0%	P=0.677, I <sup>2</sup> =0%	P=0.703, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders		Moderate	2.1% (0.7, 6.3)	5.3% (2.0, 13.4)	P=0.033, I <sup>2</sup> =0%	P=0.891, I <sup>2</sup> =0%	0.375 (0.081, 1.739)	0.388 (0.089, 1.699) 0.209	-0.033 (-0.089, 0.023)	P=0.260, I <sup>2</sup> =2106%	P=0.256, I <sup>2</sup> =2260%	P=0.481, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Cough		18.9% (13.3, 26.1)	14.7% (8.3, 24.6)	P=0.001 , I <sup>2</sup> =89.8 %	P=0.455 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Cough	Mild	18.9% (13.3, 26.1)	10.7% (5.4, 19.9)	P=0.001 , I <sup>2</sup> =89.8 %	P=0.580 , I <sup>2</sup> =0%	1.993 (0.854, 4.652)	1.784 (0.859, 3.706) 0.121	0.084 (-0.010 - 0.178)	P=0.186, I <sup>2</sup> =428 0%	P=0.227, I <sup>2</sup> =313 6%	P=0.042, I <sup>2</sup> =758 2%	
Respiratory, thoracic and mediastinal disorders	Cough	Moderate	0%	4.0% (1.3, 11.7)	P=1.000 , I <sup>2</sup> =0%	P=0.633 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.040 (-0.084 - 0.004)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.684, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Cough	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea		2.1% (0.7, 6.3)	6.7% (2.8, 15.0)	P=0.047, I <sup>2</sup> =0%	P=0.199, I <sup>2</sup> =26%							
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Mild	2.1% (0.7, 6.3)	6.7% (2.8, 15.0)	P=0.047, I <sup>2</sup> =0%	P=0.199, I <sup>2</sup> =26%	0.297 (0.068, 1.302)	0.319 (0.080, 1.278) 0.107	-0.045 (-0.106, 0.015)	P=0.649, I <sup>2</sup> =0%	P=0.629, I <sup>2</sup> =0%	P=0.675, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic		2.8% (1.1, 7.2)	2.7% (0.7, 10.0)	P=0.921, I <sup>2</sup> =0%	P=0.924, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Mild	2.8% (1.1, 7.2)	2.7% (0.7, 10.0)	P=0.921, I <sup>2</sup> =0%	P=0.924, I <sup>2</sup> =0%	1.049 (0.188, 5.865)	1.048 (0.196, 5.590) 0.956	0.001 (-0.044 - 0.047)	P=0.983, I <sup>2</sup> =0%	P=0.983, I <sup>2</sup> =0%	P=0.986, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Asthma		2.8% (1.1, 7.2)	2.7% (0.7, 10.0)	P=0.921, I <sup>2</sup> =0%	P=0.924, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Asthma	Mild	2.1% (0.7, 6.3)	1.3% (0.2, 8.9)	P=0.614, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	1.604 (0.162, 15.830)	1.588 (0.168, 15.017) 0.687	0.008 (-0.027 - 0.043)	P=0.743, I <sup>2</sup> =0%	P=0.742, I <sup>2</sup> =0%	P=0.843, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Asthma	Moderate	0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.222, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	0.507 (0.031, 8.365)	0.515 (0.033, 7.984) 0.635	-0.007 (-0.036 - 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Asthma	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Respiratory disorder		1.4% (0.4, 5.4)	1.3% (0.2, 8.9)	P=0.083, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Moderate	0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.222, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	0.507 (0.031, 8.365)	0.515 (0.033, 7.984) 0.635	-0.007 (-0.036 - 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Epistaxis		1.4% (0.4, 5.4)	0%	P=0.083, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Epistaxis	Mild	1.4% (0.4, 5.4)	0%	P=0.083, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Epistaxis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Epistaxis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal congestion		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Wheezing		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Wheezing	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Wheezing	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Wheezing	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sinus congestion		1.4% (0.4, 5.4)	0%	P=0.083, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Mild	1.4% (0.4, 5.4)	0%	P=0.083, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Allergic cough		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Allergic cough	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Allergic cough	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Allergic cough	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Laryngospasm		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Moderate	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal obstruction		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Productive cough		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Productive cough	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Respiratory, thoracic and mediastinal disorders	Productive cough	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Productive cough	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointestinal disorders			15.4% (10.3, 22.3)	18.7% (11.4, 29.1)	P=0.238 , I <sup>2</sup> =26.8%	P=0.359 , I <sup>2</sup> =0%							
Gastrointestinal disorders		Mild	15.4% (10.3, 22.3)	16.0% (9.3, 26.1)	P=0.238 , I <sup>2</sup> =26.8%	P=0.093 , I <sup>2</sup> =60%	0.955 (0.447, 2.043)	0.961 (0.500, 1.848) 0.906	-0.006 (-0.109, -)	P=0.048, I <sup>2</sup> =744%	P=0.051, I <sup>2</sup> =738%	P=0.035, I <sup>2</sup> =775%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Gastrointestinal disorders		Moderate	0%	2.7% (0.7, 10.0)	P=1.000, I <sup>2</sup> =0%	P=0.078, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.063 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Diarrhoea		4.9% (2.4, 9.9)	6.7% (2.8, 15.0)	P=0.602, I <sup>2</sup> =0%	P=0.199, I <sup>2</sup> =26%							
Gastrointestinal disorders	Diarrhoea	Mild	4.9% (2.4, 9.9)	6.7% (2.8, 15.0)	P=0.602, I <sup>2</sup> =0%	P=0.199, I <sup>2</sup> =26%	0.723 (0.222, 2.354)	0.735 (0.240, 2.254) 0.59	-0.018 (-0.084 - 0.049)	P=0.208, I <sup>2</sup> =369%	P=0.212, I <sup>2</sup> =358%	P=0.150, I <sup>2</sup> =518%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Gastrointestinal disorders	Diarrhoea	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Diarrhoea	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Vomiting		4.2% (1.9, 9.0)	2.7% (0.7, 10.0)	P=0.063, I <sup>2</sup> =60.8%	P=0.078, I <sup>2</sup> =0%							
Gastrointestinal disorders	Vomiting	Mild	4.2% (1.9, 9.0)	1.3% (0.2, 8.9)	P=0.063, I <sup>2</sup> =60.8%	P=0.215, I <sup>2</sup> =0%	3.267 (0.379, 28.153)	3.100 (0.387, 24.858)	0.028 (-0.013 - 0.070)	P=0.648, I <sup>2</sup> =0%	P=0.662, I <sup>2</sup> =0%	P=0.334, I <sup>2</sup> =0%	



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Gastrointestinal disorders	Vomiting	Moderate	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Vomiting	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Nausea		2.1% (0.7, 6.3)	1.3% (0.2, 8.9)	P=0.500, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%							
Gastrointestinal disorders	Nausea	Mild	2.1% (0.7, 6.3)	0%	P=0.500, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.021 (-0.003 - 0.044)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.567, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Gastrointesti nal disorders	Nausea	Moderate	0%	1.3% (0.2, 8.9)	P=1.000 , I <sup>2</sup> =0%	P=0.215 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
Gastrointesti nal disorders	Nausea	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Abdominal pain		0%	1.3% (0.2, 8.9)	P=1.000 , I <sup>2</sup> =0%	P=0.260 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Abdominal pain	Mild	0%	1.3% (0.2, 8.9)	P=1.000 , I <sup>2</sup> =0%	P=0.260 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Gastrointestinal disorders	Abdominal pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal pain upper		2.1% (0.7, 6.3)	0%	P=0.500, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal pain upper	Mild	2.1% (0.7, 6.3)	0%	P=0.500, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.021 (-0.003 - 0.044)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.567, I <sup>2</sup> =0%	
Gastrointestinal disorders	Abdominal pain upper	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Gastrointestinal disorders	Abdominal pain upper	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Dyspepsia		2.1% (0.7, 6.3)	1.3% (0.2, 8.9)	P=0.614, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Gastrointestinal disorders	Dyspepsia	Mild	2.1% (0.7, 6.3)	1.3% (0.2, 8.9)	P=0.614, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	1.604 (0.162, 15.830)	1.588 (0.168, 15.017) 0.687	0.008 (-0.027 - 0.043)	P=0.743, I <sup>2</sup> =0%	P=0.742, I <sup>2</sup> =0%	P=0.843, I <sup>2</sup> =0%	
Gastrointestinal disorders	Dyspepsia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Gastrointestinal disorders	Dyspepsia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Constipation		1.4% (0.4, 5.4)	1.3% (0.2, 8.9)	P=0.083, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Gastrointestinal disorders	Constipation	Mild	1.4% (0.4, 5.4)	1.3% (0.2, 8.9)	P=0.083, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	1.042 (0.094, 11.600)	1.042 (0.093, 11.715) 0.973	0.001 (-0.032, 0.033)	P=0.214, I <sup>2</sup> =3521%	P=0.216, I <sup>2</sup> =3470%	P=0.217, I <sup>2</sup> =3435%	
Gastrointestinal disorders	Constipation	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Gastrointestinal disorders	Constipation	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Toothache		0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.222, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%							
Gastrointestinal disorders	Toothache	Mild	0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.222, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	0.507 (0.031, 8.365)	0.515 (0.033, 7.984) 0.635	-0.007 (-0.036 - 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Toothache	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Toothache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Gastrointestinal disorders	Abdominal discomfort		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal discomfort	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Abdominal discomfort	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Gastrointestinal disorders	Enteritis		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Gastrointestinal disorders	Enteritis	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Enteritis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Enteritis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Gastrointestinal disorders	Gastrointestinal disorder		1.4% (0.4, 5.4)	0%	P=0.106, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastrointestinal disorder	Mild	1.4% (0.4, 5.4)	0%	P=0.106, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Gastrointestinal disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastrointestinal disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastric disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Gastrointesti nal disorders	Gastric disorder	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastric disorder	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastric disorder	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastrointesti nal motility disorder		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Gastrointesti nal disorders	Gastrointesti nal motility disorder	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastrointesti nal motility disorder	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastrointesti nal motility disorder	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Aphthous ulcer		0%	1.3% (0.2, 8.9)	P=1.000 , I <sup>2</sup> =0%	P=0.215 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Aphthous ulcer	Mild	0%	1.3% (0.2, 8.9)	P=1.000 , I <sup>2</sup> =0%	P=0.215 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Gastrointestinal disorders	Aphthous ulcer	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Aphthous ulcer	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Lip swelling		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Lip swelling	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Gastrointestinal disorders	Lip swelling	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Lip swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal distension		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal distension	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal distension	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Gastrointestinal disorders	Abdominal distension	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Noninfective gingivitis		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Gastrointestinal disorders	Noninfective gingivitis	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Noninfective gingivitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Gastrointestinal disorders	Noninfective gingivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions			17.5% (12.1, 24.6)	22.7% (14.6, 33.5)	P=0.200, I <sup>2</sup> =37.3%	P=0.282, I <sup>2</sup> =11%							
General disorders and administration site conditions		Mild	14.7% (9.8, 21.5)	21.3% (13.5, 32.0)	P=0.154, I <sup>2</sup> =48.6%	P=0.405, I <sup>2</sup> =0%	0.635 (0.307, 1.311)	0.691 (0.386, 1.239) 0.215	-0.066 (-0.175, 0.043)	P=0.777, I <sup>2</sup> =0%	P=0.730, I <sup>2</sup> =0%	P=0.962, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administration site conditions		Moderate	2.8% (1.1, 7.2)	1.3% (0.2, 8.9)	P=0.921, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	2.139 (0.234, 19.572)	2.109 (0.238, 18.695) 0.503	0.015 (-0.023 - 0.052)	P=0.564, I <sup>2</sup> =0%	P=0.562, I <sup>2</sup> =0%	P=0.622, I <sup>2</sup> =0%	
General disorders and administration site conditions		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administration site conditions	Pyrexia		14.0% (9.2, 20.7)	16.0% (9.3, 26.1)	P=0.464, I <sup>2</sup> =0%	P=0.307, I <sup>2</sup> =0%							
General disorders and administration site conditions	Pyrexia	Mild	11.9% (7.5, 18.3)	14.7% (8.3, 24.6)	P=0.277, I <sup>2</sup> =12.3%	P=0.455, I <sup>2</sup> =0%	0.787 (0.347, 1.786)	0.814 (0.403, 1.643) 0.565	-0.027 (-0.123, 0.068)	P=0.929, I <sup>2</sup> =0%	P=0.913, I <sup>2</sup> =0%	P=0.981, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administrati on site conditions	Pyrexia	Moderate	2.1% (0.7, 6.3)	1.3% (0.2, 8.9)	P=0.500 , I <sup>2</sup> =0%	P=0.260 , I <sup>2</sup> =0%	1.583 (0.162, 15.472)	1.575 (0.164, 15.150) 0.694	0.008 (-0.027 - 0.043)	P=0.40 1, I <sup>2</sup> =0%	P=0.40 1, I <sup>2</sup> =0%	P=0.39 7, I <sup>2</sup> =0%	
General disorders and administrati on site conditions	Pyrexia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site pain		2.1% (0.7, 6.3)	0%	P=0.047 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administrati on site conditions	Injection site pain	Mild	2.1% (0.7, 6.3)	0%	P=0.047 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.021 (-0.002 - 0.045)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
General disorders and administrati on site conditions	Injection site pain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administrati on site conditions	Injection site pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site pruritus		1.4% (0.4, 5.4)	1.3% (0.2, 8.9)	P=0.106 , I <sup>2</sup> =0%	P=0.260 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administrati on site conditions	Injection site pruritus	Mild	1.4% (0.4, 5.4)	1.3% (0.2, 8.9)	P=0.106 , I <sup>2</sup> =0%	P=0.260 , I <sup>2</sup> =0%	1.068 (0.094, 12.158)	1.067 (0.100, 11.406) 0.957	0.001 (-0.031 - 0.033)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
General disorders and administrati on site conditions	Injection site pruritus	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site pruritus	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administrati on site conditions	Fatigue		0.7% (0.1, 4.8)	0%	P=0.222 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Fatigue	Mild	0.7% (0.1, 4.8)	0%	P=0.222 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administration site conditions	Fatigue	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Fatigue	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administrati on site conditions	Injection site swelling		0%	1.3% (0.2, 8.9)	P=1.000 , I <sup>2</sup> =0%	P=0.215 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site swelling	Mild	0%	1.3% (0.2, 8.9)	P=1.000 , I <sup>2</sup> =0%	P=0.215 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
General disorders and administrati on site conditions	Injection site swelling	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administration site conditions	Injection site swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site erythema		0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.255, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administrati on site conditions	Injection site erythema	Mild	0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.255 , I <sup>2</sup> =0%	P=0.260 , I <sup>2</sup> =0%	0.527 (0.032, 8.656)	0.533 (0.034, 8.302) 0.654	-0.006 (-0.035 - 0.023)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
General disorders and administrati on site conditions	Injection site erythema	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administrati on site conditions	Injection site erythema	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site reaction		1.4% (0.4, 5.4)	0%	P=0.106 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site reaction	Mild	0.7% (0.1, 4.8)	0%	P=0.255 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administrati on site conditions	Injection site reaction	Moderate	0.7% (0.1, 4.8)	0%	P=0.255 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
General disorders and administrati on site conditions	Injection site reaction	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administrati on site conditions	Face oedema		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Face oedema	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administrati on site conditions	Face oedema	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Face oedema	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Gait disturbance		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administrati on site conditions	Gait disturbance	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Gait disturbance	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administration site conditions	Gait disturbance	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Influenza like illness		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administration site conditions	Influenza like illness	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Influenza like illness	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Influenza like illness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administrati on site conditions	Injection site atrophy		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site atrophy	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administration site conditions	Injection site atrophy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site atrophy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administrati on site conditions	Injection site urticaria		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site urticaria	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site urticaria	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administration site conditions	Injection site urticaria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Vaccination site pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administration site conditions	Vaccination site pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Vaccination site pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administrati on site conditions	Vaccination site pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Medical device discomfort		0%	1.3% (0.2, 8.9)	P=1.000 , I <sup>2</sup> =0%	P=0.215 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Medical device discomfort	Mild	0%	1.3% (0.2, 8.9)	P=1.000 , I <sup>2</sup> =0%	P=0.215 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administration site conditions	Medical device discomfort	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Medical device discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administrati on site conditions	Pain		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Pain	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administrati on site conditions	Pain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site bruising		0%	1.3% (0.2, 8.9)	P=1.000 , I <sup>2</sup> =0%	P=0.260 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administrati on site conditions	Injection site bruising	Mild	0%	1.3% (0.2, 8.9)	P=1.000 , I <sup>2</sup> =0%	P=0.260 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
General disorders and administrati on site conditions	Injection site bruising	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administration site conditions	Injection site bruising	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site haemorrhage		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administration site conditions	Injection site haemorrhage	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Injection site haemorrhage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site haemorrhage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administrati on site conditions	Peripheral swelling		0.7% (0.1, 4.8)	0%	P=0.255 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Peripheral swelling	Mild	0.7% (0.1, 4.8)	0%	P=0.255 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
General disorders and administrati on site conditions	Peripheral swelling	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Peripheral swelling	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Nervous system disorders			7.7% (4.3, 13.4)	10.7% (5.4, 19.9)	P=0.001 , I <sup>2</sup> =82.6 %	P=0.342 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Nervous system disorders		Mild	5.6% (2.8, 10.8)	8.0% (3.6, 16.7)	P=0.015, I <sup>2</sup> =74.4%	P=0.865, I <sup>2</sup> =0%	0.673 (0.223, 2.031)	0.693 (0.249, 1.925) 0.481	-0.025 (-0.096, 0.047)	P=0.147, I <sup>2</sup> =524%	P=0.145, I <sup>2</sup> =530%	P=0.272, I <sup>2</sup> =170%	
Nervous system disorders		Moderate	2.1% (0.7, 6.3)	2.7% (0.7, 10.0)	P=0.033, I <sup>2</sup> =0%	P=0.078, I <sup>2</sup> =0%	0.762 (0.121, 4.783)	0.772 (0.135, 4.408) 0.771	-0.006 (-0.049, 0.037)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Nervous system disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Headache		6.3% (3.3, 11.7)	9.3% (4.5, 18.3)	P=0.000, I <sup>2</sup> =0%	P=0.560, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Nervous system disorders	Headache	Mild	4.2% (1.9, 9.0)	6.7% (2.8, 15.0)	P=0.002, I <sup>2</sup> =0%	P=0.756, I <sup>2</sup> =0%	0.608 (0.179, 2.068)	0.622 (0.194, 1.994) 0.425	-0.025 (-0.091, 0.040)	P=0.070, I <sup>2</sup> =6962%	P=0.071, I <sup>2</sup> =6938%	P=0.106, I <sup>2</sup> =6164%	
Nervous system disorders	Headache	Moderate	2.1% (0.7, 6.3)	2.7% (0.7, 10.0)	P=0.033, I <sup>2</sup> =0%	P=0.078, I <sup>2</sup> =0%	0.762 (0.121, 4.783)	0.772 (0.135, 4.408) 0.771	-0.006 (-0.049, 0.037)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Nervous system disorders	Headache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Dizziness		1.4% (0.4, 5.4)	0%	P=0.944, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Nervous system disorders	Dizziness	Mild	1.4% (0.4, 5.4)	0%	P=0.944, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.033)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.718, I <sup>2</sup> =0%	
Nervous system disorders	Dizziness	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Dizziness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Post-traumatic headache		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Nervous system disorders	Post-traumatic headache	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Nervous system disorders	Post-traumatic headache	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Post-traumatic headache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Migraine		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Migraine	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Nervous system disorders	Migraine	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Migraine	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Tremor		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Tremor	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Nervous system disorders	Tremor	Moderate	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Nervous system disorders	Tremor	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications			9.8% (5.9, 15.9)	8.0% (3.6, 16.7)	P=0.185, I <sup>2</sup> =40.5%	P=0.304, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications		Mild	7.0% (3.8, 12.5)	6.7% (2.8, 15.0)	P=0.413, I <sup>2</sup> =0%	P=0.536, I <sup>2</sup> =0%	1.048 (0.344, 3.194)	1.044 (0.371, 2.936) 0.935	0.003 (-0.067 - 0.073)	P=0.975, I <sup>2</sup> =0%	P=0.974, I <sup>2</sup> =0%	P=0.991, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications		Moderate	2.8% (1.1, 7.2)	1.3% (0.2, 8.9)	P=0.257, I <sup>2</sup> =9.7%	P=0.215, I <sup>2</sup> =0%	2.120 (0.230, 19.543)	2.071 (0.239, 17.936) 0.509	0.014 (-0.023 - 0.052)	P=0.763, I <sup>2</sup> =0%	P=0.764, I <sup>2</sup> =0%	P=0.769, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Head injury		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Head injury	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Head injury	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Head injury	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Post-traumatic pain		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Post-traumatic pain	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Post-traumatic pain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Post-traumatic pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Contusion		0.7% (0.1, 4.8)	0%	P=0.222 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Contusion	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Contusion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Contusion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ligament sprain		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ligament sprain	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Ligament sprain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ligament sprain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal bite		0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.222 , I <sup>2</sup> =0%	P=0.215 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Animal bite	Mild	0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.222 , I <sup>2</sup> =0%	P=0.215 , I <sup>2</sup> =0%	0.507 (0.031, 8.365)	0.515 (0.033, 7.984) 0.635	-0.007 (-0.036 - 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Animal bite	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal bite	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Arthropod bite		0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.222, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Arthropod bite	Mild	0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.222, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	0.507 (0.031, 8.365)	0.515 (0.033, 7.984) 0.635	-0.007 (-0.036 - 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Arthropod bite	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Arthropod bite	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Skin laceration		1.4% (0.4, 5.4)	0%	P=0.106 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Skin laceration	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Skin laceration	Moderate	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Skin laceration	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Ankle fracture		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ankle fracture	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ankle fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Ankle fracture	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Concussion		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Concussion	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Concussion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Concussion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Thermal burn		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Thermal burn	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Thermal burn	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Thermal burn	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Upper limb fracture		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Upper limb fracture	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Upper limb fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Upper limb fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns first degree		0%	1.3% (0.2, 8.9)	P=1.000 , I <sup>2</sup> =0%	P=0.215 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Burns first degree	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Burns first degree	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns first degree	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Burns second degree		0.7% (0.1, 4.8)	0%	P=0.222 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns second degree	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns second degree	Moderate	0.7% (0.1, 4.8)	0%	P=0.222 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Burns second degree	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Face injury		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Face injury	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Face injury	Moderate	0.7% (0.1, 4.8)	0%	P=0.222 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Face injury	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Fall		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Fall	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Fall	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Fall	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Laceration		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Laceration	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Laceration	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Laceration	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Meniscus injury		0%	1.3% (0.2, 8.9)	P=1.000 , I <sup>2</sup> =0%	P=0.215 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Meniscus injury	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Meniscus injury	Moderate	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Meniscus injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Muscle strain		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Muscle strain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Muscle strain	Moderate	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Muscle strain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Radius fracture		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Radius fracture	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Radius fracture	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Radius fracture	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Wrist fracture		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Wrist fracture	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Wrist fracture	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Wrist fracture	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal scratch		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Animal scratch	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Animal scratch	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal scratch	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Eye injury		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Eye injury	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Eye injury	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Eye injury	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Joint injury		0.7% (0.1, 4.8)	0%	P=0.255 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Joint injury	Mild	0.7% (0.1, 4.8)	0%	P=0.255 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Injury, poisoning and procedural complications	Joint injury	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Joint injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders			8.4% (4.8, 14.2)	5.3% (2.0, 13.4)	P=0.298, I <sup>2</sup> =3.2%	P=0.236, I <sup>2</sup> =17%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Skin and subcutaneous tissue disorders		Mild	8.4% (4.8, 14.2)	4.0% (1.3, 11.7)	P=0.298, I <sup>2</sup> =3.2%	P=0.477, I <sup>2</sup> =0%	2.188 (0.602, 7.955)	2.100 (0.611, 7.215) 0.239	0.044 (-0.020 - 0.108)	P=0.273, I <sup>2</sup> =1670%	P=0.277, I <sup>2</sup> =1537%	P=0.218, I <sup>2</sup> =3401%	
Skin and subcutaneous tissue disorders		Moderate	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Skin and subcutaneous tissue disorders	Rash		1.4% (0.4, 5.4)	1.3% (0.2, 8.9)	P=0.083, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash	Mild	1.4% (0.4, 5.4)	1.3% (0.2, 8.9)	P=0.083, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	1.030 (0.090, 11.772)	1.029 (0.097, 10.963) 0.981	0.000 (-0.032, 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Rash	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Skin and subcutaneous tissue disorders	Urticaria		2.1% (0.7, 6.3)	1.3% (0.2, 8.9)	P=0.614, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria	Mild	2.1% (0.7, 6.3)	0%	P=0.614, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.021 (-0.002 - 0.045)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.615, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Urticaria	Moderate	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Skin and subcutaneous tissue disorders	Urticaria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis allergic		1.4% (0.4, 5.4)	2.7% (0.7, 10.0)	P=0.106, I <sup>2</sup> =0%	P=0.924, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis allergic	Mild	1.4% (0.4, 5.4)	2.7% (0.7, 10.0)	P=0.106, I <sup>2</sup> =0%	P=0.924, I <sup>2</sup> =0%	0.524 (0.073, 3.783)	0.530 (0.077, 3.661) 0.52	-0.013 (-0.054, 0.029)	P=0.369, I <sup>2</sup> =0%	P=0.369, I <sup>2</sup> =0%	P=0.436, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Dermatitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Skin and subcutaneous tissue disorders	Dermatitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Eczema		1.4% (0.4, 5.4)	0%	P=0.106, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Eczema	Mild	1.4% (0.4, 5.4)	0%	P=0.106, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Skin and subcutaneous tissue disorders	Eczema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Eczema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis contact		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis contact	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Skin and subcutaneous tissue disorders	Dermatitis contact	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis contact	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria papular		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Skin and subcutaneous tissue disorders	Urticaria papular	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Urticaria papular	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria papular	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Cafe au lait spots		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Skin and subcutaneous tissue disorders	Cafe au lait spots	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Cafe au lait spots	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Cafe au lait spots	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Skin and subcutaneous tissue disorders	Keratosis pilaris		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Keratosis pilaris	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Keratosis pilaris	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Keratosis pilaris	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Skin and subcutaneous tissue disorders	Petechiae		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Petechiae	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Petechiae	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Skin and subcutaneous tissue disorders	Petechiae	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Pityriasis alba		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Pityriasis alba	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Pityriasis alba	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Skin and subcutaneous tissue disorders	Pityriasis alba	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash erythematous		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash erythematous	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Skin and subcutaneous tissue disorders	Rash erythematous	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash erythematous	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash pruritic		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash pruritic	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Skin and subcutaneous tissue disorders	Rash pruritic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash pruritic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Skin and subcutaneous tissue disorders	Dermatitis	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Dermatitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dyshidrotic eczema		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Skin and subcutaneous tissue disorders	Urticaria chronic		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria chronic	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Urticaria chronic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria chronic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Eye disorders			7.7% (4.3, 13.4)	4.0% (1.3, 11.7)	P=0.153, I <sup>2</sup> =45.9%	P=0.049, I <sup>2</sup> =0%							
Eye disorders		Mild	7.0% (3.8, 12.5)	4.0% (1.3, 11.7)	P=0.242, I <sup>2</sup> =21.3%	P=0.049, I <sup>2</sup> =0%	1.844 (0.484, 7.024)	1.765 (0.505, 6.176) 0.374	0.030 (-0.030 - 0.091)	P=0.483, I <sup>2</sup> =0%	P=0.473, I <sup>2</sup> =0%	P=0.765, I <sup>2</sup> =0%	
Eye disorders		Moderate	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Eye disorders	Refraction disorder		2.1% (0.7, 6.3)	2.7% (0.7, 10.0)	P=0.047, I <sup>2</sup> =0%	P=0.109, I <sup>2</sup> =0%							
Eye disorders	Refraction disorder	Mild	2.1% (0.7, 6.3)	2.7% (0.7, 10.0)	P=0.047, I <sup>2</sup> =0%	P=0.109, I <sup>2</sup> =0%	0.792 (0.127, 4.944)	0.800 (0.139, 4.592) 0.802	-0.005 (-0.048, 0.038)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Refraction disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Refraction disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Eye disorders	Conjunctivitis allergic		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Conjunctivitis allergic	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Conjunctivitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Conjunctivitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye swelling		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Eye disorders	Eye swelling	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye swelling	Moderate	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Eye swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Myopia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Eye disorders	Myopia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Myopia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Myopia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Strabismus		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Eye disorders	Strabismus	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Strabismus	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Strabismus	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Papilloedema		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Papilloedema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Eye disorders	Papilloedema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Papilloedema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Hypermetropia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Hypermetropia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Hypermetropia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Eye disorders	Hypermetro pia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Astigmatism		0.7% (0.1, 4.8)	0%	P=0.222 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Astigmatism	Mild	0.7% (0.1, 4.8)	0%	P=0.222 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Eye disorders	Astigmatism	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Eye disorders	Astigmatism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye haemorrhage		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye haemorrhage	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Eye haemorrhage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Eye disorders	Eye haemorrhage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Corneal epithelium defect		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Corneal epithelium defect	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Corneal epithelium defect	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Corneal epithelium defect	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Eye disorders	Eye pain		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye pain	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Eye pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Eye disorders	Vernal keratoconjunctivitis		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Eye disorders	Vernal keratoconjunctivitis	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Vernal keratoconjunctivitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Vernal keratoconjunctivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Eye disorders	Vitreous opacities		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Vitreous opacities	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Vitreous opacities	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Vitreous opacities	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Xerophthal mia		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Eye disorders	Xerophthal mia	Mild	0%	1.3% (0.2, 8.9)	P=1.000 , I <sup>2</sup> =0%	P=0.260 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Eye disorders	Xerophthal mia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Xerophthal mia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Musculoskeletal and connective tissue disorders			5.6% (2.8, 10.8)	4.0% (1.3, 11.7)	P=0.382, I <sup>2</sup> =0%	P=0.030, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders		Mild	5.6% (2.8, 10.8)	4.0% (1.3, 11.7)	P=0.382, I <sup>2</sup> =0%	P=0.030, I <sup>2</sup> =0%	1.415 (0.360, 5.558)	1.385 (0.384, 4.998) 0.619	0.015 (-0.042, 0.073)	P=0.343, I <sup>2</sup> =0%	P=0.339, I <sup>2</sup> =0%	P=0.430, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Musculoskeletal and connective tissue disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Pain in extremity		1.4% (0.4, 5.4)	4.0% (1.3, 11.7)	P=0.106, I <sup>2</sup> =0%	P=0.030, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Pain in extremity	Mild	1.4% (0.4, 5.4)	4.0% (1.3, 11.7)	P=0.106, I <sup>2</sup> =0%	P=0.030, I <sup>2</sup> =0%	0.351 (0.060, 2.072)	0.351 (0.060, 2.067) 0.247	-0.026 (-0.075, 0.023)	P=0.089, I <sup>2</sup> =655 3%	P=0.093, I <sup>2</sup> =646 7%	P=0.031, I <sup>2</sup> =786 4%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Musculoskeletal and connective tissue disorders	Pain in extremity	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Pain in extremity	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthralgia		2.8% (1.1, 7.2)	0%	P=0.257, I <sup>2</sup> =9.7%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Musculoskeletal and connective tissue disorders	Arthralgia	Mild	2.8% (1.1, 7.2)	0%	P=0.257, I <sup>2</sup> =9.7%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.028 (0.001 - 0.055)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.364, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders	Arthralgia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthralgia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Musculoskeletal and connective tissue disorders	Musculoskeletal pain		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck pain		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Musculoskeletal and connective tissue disorders	Neck pain	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders	Neck pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Musculoskeletal and connective tissue disorders	Back pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Back pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Back pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Musculoskeletal and connective tissue disorders	Back pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck mass		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck mass	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Musculoskeletal and connective tissue disorders	Neck mass	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck mass	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Musculoskeletal and connective tissue disorders	Pain in jaw		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Pain in jaw	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Pain in jaw	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Musculoskeletal and connective tissue disorders	Pain in jaw	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Synovial cyst		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Synovial cyst	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Musculoskeletal and connective tissue disorders	Synovial cyst	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Synovial cyst	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthritis reactive		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Musculoskel etal and connective tissue disorders	Arthritis reactive	Mild	0.7% (0.1, 4.8)	0%	P=0.222 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Musculoskel etal and connective tissue disorders	Arthritis reactive	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Arthritis reactive	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Musculoskeletal and connective tissue disorders	Scoliosis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Scoliosis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Musculoskel etal and connective tissue disorders	Scoliosis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Scoliosis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Metabolism and nutrition disorders			6.3% (3.3, 11.7)	6.7% (2.8, 15.0)	P=0.000 , I <sup>2</sup> =0%	P=0.010 , I <sup>2</sup> =0%							
Metabolism and nutrition disorders		Mild	6.3% (3.3, 11.7)	6.7% (2.8, 15.0)	P=0.000 , I <sup>2</sup> =0%	P=0.010 , I <sup>2</sup> =0%	0.955 (0.297, 3.068)	0.960 (0.345, 2.672) 0.938	-0.003 (-0.070 - 0.064)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Metabolism and nutrition disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypertriglyceridaemia		4.2% (1.9, 9.0)	1.3% (0.2, 8.9)	P=0.005, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Metabolism and nutrition disorders	Hypertriglyceridaemia	Mild	4.2% (1.9, 9.0)	1.3% (0.2, 8.9)	P=0.005, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	3.391 (0.394, 29.204)	3.200 (0.399, 25.664) 0.274	0.029 (-0.012, 0.071)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Hypertriglyceridaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypertriglyceridaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypercholesterolaemia		2.1% (0.7, 6.3)	2.7% (0.7, 10.0)	P=0.047, I <sup>2</sup> =0%	P=0.109, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Metabolism and nutrition disorders	Hypercholesterolaemia	Mild	2.1% (0.7, 6.3)	2.7% (0.7, 10.0)	P=0.047, I <sup>2</sup> =0%	P=0.109, I <sup>2</sup> =0%	0.792 (0.127, 4.944)	0.800 (0.139, 4.592) 0.802	-0.005 (-0.048, 0.038)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Hypercholesterolaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypercholesterolaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Metabolism and nutrition disorders	Hyperuricaemia		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperuricaemia	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Hyperuricaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperuricaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Metabolism and nutrition disorders	Decreased appetite		0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.255, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Decreased appetite	Mild	0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.255, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	0.527 (0.032, 8.656)	0.533 (0.034, 8.302) 0.654	-0.006 (-0.035, 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Decreased appetite	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Metabolism and nutrition disorders	Decreased appetite	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Polydipsia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Polydipsia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Polydipsia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Metabolism and nutrition disorders	Polydipsia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperglycaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperglycaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Metabolism and nutrition disorders	Hyperglycaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperglycaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Calcium deficiency		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Calcium deficiency	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Metabolism and nutrition disorders	Calcium deficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Calcium deficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperlipidaemia		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Metabolism and nutrition disorders	Hyperlipidaemia	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Hyperlipidaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperlipidaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders			3.5% (1.5, 8.1)	6.7% (2.8, 15.0)	P=0.129, I <sup>2</sup> =45.5%	P=0.113, I <sup>2</sup> =50%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Endocrine disorders		Mild	2.1% (0.7, 6.3)	6.7% (2.8, 15.0)	P=0.500, I <sup>2</sup> =0%	P=0.113, I <sup>2</sup> =50%	0.293 (0.068, 1.269)	0.312 (0.077, 1.259) 0.102	-0.046 (-0.107 - 0.015)	P=0.631, I <sup>2</sup> =0%	P=0.656, I <sup>2</sup> =0%	P=0.161, I <sup>2</sup> =4902%	
Endocrine disorders		Moderate	1.4% (0.4, 5.4)	0%	P=0.083, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Secondary hypothyroidism		2.1% (0.7, 6.3)	2.7% (0.7, 10.0)	P=0.033, I <sup>2</sup> =0%	P=0.078, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Endocrine disorders	Secondary hypothyroidism	Mild	1.4% (0.4, 5.4)	2.7% (0.7, 10.0)	P=0.083, I <sup>2</sup> =0%	P=0.078, I <sup>2</sup> =0%	0.500 (0.067, 3.709)	0.515 (0.076, 3.501) 0.497	-0.013 (-0.054 - 0.028)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Secondary hypothyroidism	Moderate	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Secondary hypothyroidism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Hypothyroidism		0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.255, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Endocrine disorders	Hypothyroidism	Mild	0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.255, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	0.527 (0.033, 8.317)	0.527 (0.034, 8.219) 0.648	-0.006 (-0.036 - 0.023)	P=0.329, I <sup>2</sup> =0%	P=0.330, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =12%	
Endocrine disorders	Hypothyroidism	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Hypothyroidism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Secondary adrenocortical insufficiency		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Endocrine disorders	Secondary adrenocortical insufficiency	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Secondary adrenocortical insufficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Secondary adrenocortical insufficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Diabetes insipidus		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%							
Endocrine disorders	Diabetes insipidus	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Endocrine disorders	Diabetes insipidus	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Diabetes insipidus	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Adrenal insufficiency		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Adrenal insufficiency	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Endocrine disorders	Adrenal insufficiency	Moderate	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Adrenal insufficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Precocious puberty		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Endocrine disorders	Precocious puberty	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Endocrine disorders	Precocious puberty	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Precocious puberty	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders			5.6% (2.8, 10.8)	4.0% (1.3, 11.7)	P=0.555, I <sup>2</sup> =0%	P=0.477, I <sup>2</sup> =0%							
Blood and lymphatic system disorders		Mild	4.9% (2.4, 9.9)	4.0% (1.3, 11.7)	P=0.798, I <sup>2</sup> =0%	P=0.477, I <sup>2</sup> =0%	1.233 (0.310, 4.902)	1.222 (0.326, 4.583)	0.009 (-0.048, 0.066)	P=0.470, I <sup>2</sup> =0%	P=0.470, I <sup>2</sup> =0%	P=0.472, I <sup>2</sup> =0%	



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Blood and lymphatic system disorders		Moderate	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Anaemia		0.7% (0.1, 4.8)	2.7% (0.7, 10.0)	P=0.222, I <sup>2</sup> =0%	P=0.924, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Anaemia	Mild	0.7% (0.1, 4.8)	2.7% (0.7, 10.0)	P=0.222, I <sup>2</sup> =0%	P=0.924, I <sup>2</sup> =0%	0.253 (0.022, 2.875)	0.259 (0.024, 2.840) 0.269	-0.020 (-0.059 - 0.019)	P=0.592, I <sup>2</sup> =0%	P=0.589, I <sup>2</sup> =0%	P=0.703, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Blood and lymphatic system disorders	Anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Iron deficiency anaemia		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Blood and lymphatic system disorders	Iron deficiency anaemia	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Iron deficiency anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Iron deficiency anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenopathy		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Blood and lymphatic system disorders	Lymphadenopathy	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Lymphadenopathy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenopathy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Blood and lymphatic system disorders	Neutropenia		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Neutropenia	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Neutropenia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Neutropenia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Blood and lymphatic system disorders	Granulocytopenia		1.4% (0.4, 5.4)	0%	P=0.106, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Granulocytopenia	Mild	1.4% (0.4, 5.4)	0%	P=0.106, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Granulocytopenia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Blood and lymphatic system disorders	Granulocytopenia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenitis		1.4% (0.4, 5.4)	0%	P=0.106, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenitis	Mild	1.4% (0.4, 5.4)	0%	P=0.106, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Lymphadenitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Blood and lymphatic system disorders	Lymphadenitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Hypochromic anaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Hypochromic anaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Blood and lymphatic system disorders	Hypochromic anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Hypochromic anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Thymus disorder		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Thymus disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Blood and lymphatic system disorders	Thymus disorder	Moderate	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Thymus disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders			2.8% (1.1, 7.2)	4.0% (1.3, 11.7)	P=0.014, I <sup>2</sup> =0%	P=0.477, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Immune system disorders		Mild	2.8% (1.1, 7.2)	4.0% (1.3, 11.7)	P=0.014, I <sup>2</sup> =0%	P=0.477, I <sup>2</sup> =0%	0.676 (0.145, 3.156)	0.689 (0.159, 2.978) 0.618	-0.012 (-0.064, 0.039)	P=0.342, I <sup>2</sup> =0%	P=0.339, I <sup>2</sup> =0%	P=0.522, I <sup>2</sup> =0%	
Immune system disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Seasonal allergy		1.4% (0.4, 5.4)	1.3% (0.2, 8.9)	P=0.083, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%							
Immune system disorders	Seasonal allergy	Mild	1.4% (0.4, 5.4)	1.3% (0.2, 8.9)	P=0.083, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	1.030 (0.090, 11.772)	1.029 (0.097, 10.963) 0.981	0.000 (-0.032, 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Immune system disorders	Seasonal allergy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Seasonal allergy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Hypersensitivity		0%	2.7% (0.7, 10.0)	P=1.000, I <sup>2</sup> =0%	P=0.924, I <sup>2</sup> =0%							
Immune system disorders	Hypersensitivity	Mild	0%	2.7% (0.7, 10.0)	P=1.000, I <sup>2</sup> =0%	P=0.924, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.027 (-0.063 - 0.010)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.805, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Immune system disorders	Hypersensitivity	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Hypersensitivity	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Allergy to animal		1.4% (0.4, 5.4)	0%	P=0.083, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Allergy to animal	Mild	1.4% (0.4, 5.4)	0%	P=0.083, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Immune system disorders	Allergy to animal	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Immune system disorders	Allergy to animal	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Immune system disorders	Food allergy		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Immune system disorders	Food allergy	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Immune system disorders	Food allergy	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Immune system disorders	Food allergy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders			3.5% (1.5, 8.1)	1.3% (0.2, 8.9)	P=0.010, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%							
Reproductive system and breast disorders		Mild	3.5% (1.5, 8.1)	1.3% (0.2, 8.9)	P=0.010, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	2.634 (0.315, 22.062)	2.634 (0.312, 22.211) 0.373	0.022 (-0.018, 0.062)	P=0.076, I <sup>2</sup> =6817%	P=0.077, I <sup>2</sup> =6797%	P=0.049, I <sup>2</sup> =7409%	
Reproductive system and breast disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Reproductive system and breast disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Penile adhesion		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Penile adhesion	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Reproductiv e system and breast disorders	Penile adhesion	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Penile adhesion	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Gynaecomasia		1.4% (0.4, 5.4)	0%	P=0.106 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Gynaecomasia	Mild	1.4% (0.4, 5.4)	0%	P=0.106 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.033)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Reproductive system and breast disorders	Gynaecomastia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Gynaecomastia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Genital discomfort		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Reproductive system and breast disorders	Genital discomfort	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.215, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Reproductive system and breast disorders	Genital discomfort	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Genital discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Balanoposthitis		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Reproductive system and breast disorders	Balanoposthitis	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Reproductive system and breast disorders	Balanoposthitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Balanoposthitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Reproductive system and breast disorders	Pelvic fluid collection		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Pelvic fluid collection	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Reproductive system and breast disorders	Pelvic fluid collection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Pelvic fluid collection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Reproductive system and breast disorders	Testicular appendage torsion		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Testicular appendage torsion	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Reproductive system and breast disorders	Testicular appendage torsion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Reproductive system and breast disorders	Testicular appendage torsion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders			1.4% (0.4, 5.4)	1.3% (0.2, 8.9)	P=0.944, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Ear and labyrinth disorders		Mild	1.4% (0.4, 5.4)	1.3% (0.2, 8.9)	P=0.944, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	1.055 (0.094, 11.877)	1.054 (0.096, 11.558) 0.965	0.001 (-0.032, 0.033)	P=0.586, I <sup>2</sup> =0%	P=0.586, I <sup>2</sup> =0%	P=0.604, I <sup>2</sup> =0%	
Ear and labyrinth disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Ear and labyrinth disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Ear pain		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Ear pain	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Ear and labyrinth disorders	Ear pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Ear pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Ear and labyrinth disorders	Cerumen impaction		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Cerumen impaction	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Ear and labyrinth disorders	Cerumen impaction	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Cerumen impaction	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Ear and labyrinth disorders	Motion sickness		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Motion sickness	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Ear and labyrinth disorders	Motion sickness	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Motion sickness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Psychiatric disorders			2.1% (0.7, 6.3)	0%	P=0.033, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders		Mild	1.4% (0.4, 5.4)	0%	P=0.083, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.014 (-0.005 - 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Psychiatric disorders		Moderate	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Psychiatric disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Psychiatric disorders	Attention deficit/hyper activity disorder		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Attention deficit/hyper activity disorder	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Psychiatric disorders	Attention deficit/hyper activity disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Attention deficit/hyper activity disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Affect lability		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Psychiatric disorders	Affect lability	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Affect lability	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Affect lability	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Depressive symptom		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Psychiatric disorders	Depressive symptom	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Depressive symptom	Moderate	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Psychiatric disorders	Depressive symptom	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Enuresis		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Psychiatric disorders	Enuresis	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Psychiatric disorders	Enuresis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Enuresis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders			2.1% (0.7, 6.3)	0%	P=0.614, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders		Mild	2.1% (0.7, 6.3)	0%	P=0.614, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.021 (-0.002 - 0.045)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.615, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Cardiac disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinus tachycardia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinus tachycardia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Cardiac disorders	Sinus tachycardia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinus tachycardia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinoatrial block		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinoatrial block	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Cardiac disorders	Sinoatrial block	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Cardiac disorders	Sinoatrial block	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Tachycardia		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Tachycardia	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Cardiac disorders	Tachycardia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Cardiac disorders	Tachycardia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Myocarditis		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Myocarditis	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Cardiac disorders	Myocarditis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Cardiac disorders	Myocarditis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Wandering pacemaker		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Wandering pacemaker	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Cardiac disorders	Wandering pacemaker	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Wandering pacemaker	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			2.1% (0.7, 6.3)	0%	P=0.033 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Mild	2.1% (0.7, 6.3)	0%	P=0.033 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.021 (-0.003 - 0.044)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma		1.4% (0.4, 5.4)	0%	P=0.083 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Mild	1.4% (0.4, 5.4)	0%	P=0.083, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma		0.7% (0.1, 4.8)	0%	P=0.222 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Mild	0.7% (0.1, 4.8)	0%	P=0.222 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Renal and urinary disorders			0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.222, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							
Renal and urinary disorders		Mild	0.7% (0.1, 4.8)	1.3% (0.2, 8.9)	P=0.222, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	0.521 (0.032, 8.438)	0.521 (0.032, 8.539) 0.648	-0.006 (-0.036 - 0.023)	P=0.34 4, I <sup>2</sup> =0%	P=0.34 5, I <sup>2</sup> =0%	P=0.34 7, I <sup>2</sup> =0%	
Renal and urinary disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Polyuria		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Renal and urinary disorders	Polyuria	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Renal and urinary disorders	Polyuria	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Renal and urinary disorders	Polyuria	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Renal and urinary disorders	Pollakiuria		0.7% (0.1, 4.8)	0%	P=0.222 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Renal and urinary disorders	Pollakiuria	Mild	0.7% (0.1, 4.8)	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Renal and urinary disorders	Pollakiuria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Pollakiuria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Nocturia		0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Renal and urinary disorders	Nocturia	Mild	0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Renal and urinary disorders	Nocturia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Nocturia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders			1.4% (0.4, 5.4)	0%	P=0.944, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders		Mild	1.4% (0.4, 5.4)	0%	P=0.944, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.033)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.718, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Vascular disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Hypotension		0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Hypotension	Mild	0.7% (0.1, 4.8)	0%	P=0.222, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Vascular disorders	Hypotension	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Hypotension	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Cyanosis		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Cyanosis	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Vascular disorders	Cyanosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Cyanosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders			1.4% (0.4, 5.4)	0%	P=0.106, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders		Mild	1.4% (0.4, 5.4)	0%	P=0.106, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.014 (-0.005 - 0.033)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Baseline GH-stimulation strata: > 5 ng/mL													
Congenital, familial and genetic disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Buried penis syndrome		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Buried penis syndrome	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Congenital, familial and genetic disorders	Buried penis syndrome	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Buried penis syndrome	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Supernumerary teeth		0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Congenital, familial and genetic disorders	Supernumerary teeth	Mild	0.7% (0.1, 4.8)	0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Congenital, familial and genetic disorders	Supernumerary teeth	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Supernumerary teeth	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Hepatobiliary disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders	Hepatomegaly		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders	Hepatomegaly	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.20.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL													
Hepatobiliary disorders	Hepatomegaly	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders	Hepatomegaly	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.													

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Any adverse event			88.1% (81.9, 92.4)	83.3% (73.8, 89.9)	P=0.000 , I <sup>2</sup> =90.7 %	P=0.004 , I <sup>2</sup> =85%							P=0.644
Any adverse event		Mild	69.5% (61.7, 76.3)	64.3% (53.5, 73.8)	P=0.000 , I <sup>2</sup> =96.1 %	P=0.000 , I <sup>2</sup> =94%	1.389 (0.731, 2.638)	1.089 (0.918, 1.291) 0.329	0.057 (-0.055 - 0.168)	P=0.843, I <sup>2</sup> =0%	P=0.373, I <sup>2</sup> =0%	P=0.567, I <sup>2</sup> =0%	P=0.897
Any adverse event		Moderate	17.2% (12.0, 24.1)	19.0% (12.0, 28.9)	P=0.001 , I <sup>2</sup> =88.9 %	P=0.005 , I <sup>2</sup> =85%	0.862 (0.420, 1.767)	0.894 (0.521, 1.533) 0.683	-0.020 (-0.120 - 0.079)	P=0.797, I <sup>2</sup> =0%	P=0.834, I <sup>2</sup> =0%	P=0.642, I <sup>2</sup> =0%	P=0.668



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Any adverse event		Severe	1.3% (0.3, 5.1)	0%	P=0.887, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.031)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.738, I <sup>2</sup> =0%	P=0.686
Infections and infestations			58.3% (50.3, 65.9)	64.3% (53.5, 73.8)	P=0.589, I <sup>2</sup> =0%	P=0.719, I <sup>2</sup> =0%							P=0.635
Infections and infestations		Mild	47.7% (39.8, 55.6)	48.8% (38.3, 59.4)	P=0.015, I <sup>2</sup> =82.8%	P=0.025, I <sup>2</sup> =79%	0.962 (0.557, 1.663)	0.981 (0.750, 1.284) 0.89	-0.009 (-0.139 - 0.121)	P=0.734, I <sup>2</sup> =0%	P=0.755, I <sup>2</sup> =0%	P=0.730, I <sup>2</sup> =0%	P=0.927
Infections and infestations		Moderate	9.3% (5.6, 15.0)	15.5% (9.2, 24.9)	P=0.001, I <sup>2</sup> =86.9%	P=0.009, I <sup>2</sup> =83%	0.522 (0.225, 1.215)	0.590 (0.299, 1.163) 0.128	-0.064 (-0.151 - 0.023)	P=0.656, I <sup>2</sup> =0%	P=0.571, I <sup>2</sup> =0%	P=0.483, I <sup>2</sup> =0%	P=0.763

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations		Severe	1.3% (0.3, 5.1)	0%	P=0.887, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.031)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.738, I <sup>2</sup> =0%	P=0.686
Infections and infestations	Upper respiratory tract infection		27.8% (21.3, 35.5)	35.7% (26.2, 46.5)	P=0.000, I <sup>2</sup> =95.1 %	P=0.000, I <sup>2</sup> =94%							P=0.991
Infections and infestations	Upper respiratory tract infection	Mild	27.8% (21.3, 35.5)	29.8% (21.0, 40.3)	P=0.000, I <sup>2</sup> =95.1 %	P=0.000, I <sup>2</sup> =92%	0.909 (0.467, 1.766)	0.948 (0.655, 1.371) 0.776	-0.015 (-0.123 - 0.092)	P=0.262, I <sup>2</sup> =204 6%	P=0.283, I <sup>2</sup> =131 5%	P=0.111, I <sup>2</sup> =605 3%	P=0.770

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Upper respiratory tract infection	Moderate	0%	6.0% (2.5, 13.5)	P=1.000, I <sup>2</sup> =0%	P=0.850, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.059 (-0.110 - -0.009)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.845, I <sup>2</sup> =0%	P=0.374
Infections and infestations	Upper respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Nasopharyngitis		5.3% (2.7, 10.2)	10.7% (5.7, 19.3)	P=0.010, I <sup>2</sup> =76.7%	P=0.029, I <sup>2</sup> =75%							P=0.784
Infections and infestations	Nasopharyngitis	Mild	4.6% (2.2, 9.4)	8.3% (4.0, 16.5)	P=0.022, I <sup>2</sup> =72.1%	P=0.017, I <sup>2</sup> =74%	0.509 (0.168, 1.547)	0.547 (0.204, 1.471) 0.232	-0.038 (-0.105 - 0.029)	P=0.941, I <sup>2</sup> =0%	P=0.979, I <sup>2</sup> =0%	P=0.196, I <sup>2</sup> =4025%	P=0.865

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Infections and infestations	Nasopharyngitis	Moderate	0.7% (0.1, 4.5)	2.4% (0.6, 9.0)	P=0.205, I <sup>2</sup> =0%	P=0.864, I <sup>2</sup> =0%	0.269 (0.024, 3.048)	0.274 (0.025, 3.011) 0.29	-0.017 (-0.052, 0.018)	P=0.593, I <sup>2</sup> =0%	P=0.590, I <sup>2</sup> =0%	P=0.731, I <sup>2</sup> =0%	P=0.886
Infections and infestations	Nasopharyngitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Pharyngitis		4.6% (2.2, 9.4)	8.3% (4.0, 16.5)	P=0.001, I <sup>2</sup> =0%	P=0.126, I <sup>2</sup> =52%							P=0.296
Infections and infestations	Pharyngitis	Mild	4.6% (2.2, 9.4)	8.3% (4.0, 16.5)	P=0.001, I <sup>2</sup> =0%	P=0.126, I <sup>2</sup> =52%	0.510 (0.167, 1.556)	0.546 (0.202, 1.477) 0.233	-0.038 (-0.105, 0.029)	P=0.251, I <sup>2</sup> =2418%	P=0.237, I <sup>2</sup> =2862%	P=0.794, I <sup>2</sup> =0%	P=0.381

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Pharyngitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.808
Infections and infestations	Pharyngitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Bronchitis		6.6% (3.6, 11.9)	3.6% (1.2, 10.5)	P=0.087 , I <sup>2</sup> =58.7%	P=0.700 , I <sup>2</sup> =0%							P=0.581
Infections and infestations	Bronchitis	Mild	5.3% (2.7, 10.2)	2.4% (0.6, 9.0)	P=0.042 , I <sup>2</sup> =64.6%	P=0.124 , I <sup>2</sup> =0%	2.374 (0.484, 11.645)	2.258 (0.497, 10.266) 0.292	0.030 (-0.018 - 0.078)	P=0.787, I <sup>2</sup> =0%	P=0.799, I <sup>2</sup> =0%	P=0.380, I <sup>2</sup> =0%	P=0.347

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Bronchitis	Moderate	1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.887, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	1.104 (0.099, 12.316)	1.102 (0.103, 11.827) 0.936	0.001 (-0.028 - 0.031)	P=0.567, I <sup>2</sup> =0%	P=0.566, I <sup>2</sup> =0%	P=0.590, I <sup>2</sup> =0%	P=0.693
Infections and infestations	Bronchitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.821
Infections and infestations	Respiratory tract infection		4.6% (2.2, 9.4)	4.8% (1.8, 12.0)	P=0.906, I <sup>2</sup> =0%	P=0.418, I <sup>2</sup> =0%							P=0.938
Infections and infestations	Respiratory tract infection	Mild	4.0% (1.8, 8.6)	4.8% (1.8, 12.0)	P=0.552, I <sup>2</sup> =0%	P=0.418, I <sup>2</sup> =0%	0.832 (0.227, 3.044)	0.839 (0.244, 2.886) 0.781	-0.008 (-0.063 - 0.047)	P=0.794, I <sup>2</sup> =0%	P=0.796, I <sup>2</sup> =0%	P=0.725, I <sup>2</sup> =0%	P=0.986

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Respiratory tract infection	Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Infections and infestations	Respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Tonsillitis		4.0% (1.8, 8.6)	6.0% (2.5, 13.5)	P=0.133, I <sup>2</sup> =42.2%	P=0.244, I <sup>2</sup> =11%							P=0.862
Infections and infestations	Tonsillitis	Mild	4.0% (1.8, 8.6)	4.8% (1.8, 12.0)	P=0.133, I <sup>2</sup> =42.2%	P=0.028, I <sup>2</sup> =0%	0.836 (0.226, 3.098)	0.846 (0.249, 2.877) 0.789	-0.007 (-0.062 - 0.047)	P=0.615, I <sup>2</sup> =0%	P=0.619, I <sup>2</sup> =0%	P=0.471, I <sup>2</sup> =0%	P=0.957

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Tonsillitis	Moderate	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.815
Infections and infestations	Tonsillitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Rhinitis		2.6% (1.0, 6.8)	3.6% (1.2, 10.5)	P=0.840, I <sup>2</sup> =0%	P=0.422, I <sup>2</sup> =0%							P=0.893
Infections and infestations	Rhinitis	Mild	2.6% (1.0, 6.8)	3.6% (1.2, 10.5)	P=0.840, I <sup>2</sup> =0%	P=0.422, I <sup>2</sup> =0%	0.731 (0.160, 3.345)	0.738 (0.170, 3.210) 0.686	-0.009 (-0.057 - 0.038)	P=0.635, I <sup>2</sup> =0%	P=0.638, I <sup>2</sup> =0%	P=0.563, I <sup>2</sup> =0%	P=0.893



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Rhinitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Rhinitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Pharyngitis streptococcal		1.3% (0.3, 5.1)	4.8% (1.8, 12.0)	P=0.073 , I <sup>2</sup> =0%	P=0.009 , I <sup>2</sup> =0%							P=0.463
Infections and infestations	Pharyngitis streptococcal	Mild	0.7% (0.1, 4.5)	2.4% (0.6, 9.0)	P=0.205 , I <sup>2</sup> =0%	P=0.068 , I <sup>2</sup> =0%	0.261 (0.023, 2.982)	0.272 (0.026, 2.901)	-0.017 (-0.052 - 0.017)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.542

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Pharyngitis streptococcal	Moderate	0.7% (0.1, 4.5)	2.4% (0.6, 9.0)	P=0.205, I <sup>2</sup> =0%	P=0.068, I <sup>2</sup> =0%	0.261 (0.023, 2.982)	0.272 (0.026, 2.901) 0.281	-0.017 (-0.052, 0.017)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.863
Infections and infestations	Pharyngitis streptococcal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Sinusitis		2.6% (1.0, 6.8)	3.6% (1.2, 10.5)	P=0.217, I <sup>2</sup> =23.2%	P=0.422, I <sup>2</sup> =0%							P=0.751
Infections and infestations	Sinusitis	Mild	1.3% (0.3, 5.1)	2.4% (0.6, 9.0)	P=0.887, I <sup>2</sup> =0%	P=0.068, I <sup>2</sup> =0%	0.544 (0.076, 3.914)	0.551 (0.080, 3.796) 0.545	-0.011 (-0.048, 0.027)	P=0.358, I <sup>2</sup> =0%	P=0.362, I <sup>2</sup> =0%	P=0.255, I <sup>2</sup> =2278%	P=0.924

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Infections and infestations	Sinusitis	Moderate	1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.073, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	1.104 (0.099, 12.299)	1.104 (0.098, 12.441) 0.936	0.001 (-0.028 - 0.031)	P=0.215, I <sup>2</sup> =349 5%	P=0.217, I <sup>2</sup> =344 8%	P=0.211, I <sup>2</sup> =361 6%	P=0.754
Infections and infestations	Sinusitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Gastroenteritis		2.0% (0.6, 6.0)	2.4% (0.6, 9.0)	P=0.027, I <sup>2</sup> =0%	P=0.864, I <sup>2</sup> =0%							P=0.622
Infections and infestations	Gastroenteritis	Mild	2.0% (0.6, 6.0)	2.4% (0.6, 9.0)	P=0.027, I <sup>2</sup> =0%	P=0.864, I <sup>2</sup> =0%	0.818 (0.133, 5.037)	0.822 (0.139, 4.850) 0.829	-0.004 (-0.044 - 0.035)	P=0.277, I <sup>2</sup> =152 1%	P=0.278, I <sup>2</sup> =149 8%	P=0.324, I <sup>2</sup> =0%	P=0.622
Infections and infestations	Gastroenteritis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Infections and infestations	Gastroenteritis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Ear infection		3.3% (1.4, 7.7)	0%	P=0.004, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.156
Infections and infestations	Ear infection	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.387
Infections and infestations	Ear infection	Moderate	2.6% (1.0, 6.8)	0%	P=0.011, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.026 (0.001 - 0.052)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.367

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Ear infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Pneumonia		2.0% (0.6, 6.0)	2.4% (0.6, 9.0)	P=0.677, I <sup>2</sup> =0%	P=0.124, I <sup>2</sup> =0%							P=0.745
Infections and infestations	Pneumonia	Mild	1.3% (0.3, 5.1)	2.4% (0.6, 9.0)	P=0.120, I <sup>2</sup> =0%	P=0.124, I <sup>2</sup> =0%	0.556 (0.076, 4.079)	0.566 (0.082, 3.890) 0.563	-0.010 (-0.047 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.887
Infections and infestations	Pneumonia	Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Pneumonia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Conjunctivitis		2.0% (0.6, 6.0)	0%	P=0.446, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.166
Infections and infestations	Conjunctivitis	Mild	1.3% (0.3, 5.1)	0%	P=0.887, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.031)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.738, I <sup>2</sup> =0%	P=0.227
Infections and infestations	Conjunctivitis	Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Infections and infestations	Conjunctivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Gastroenteritis viral		1.3% (0.3, 5.1)	0%	P=0.073, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.448
Infections and infestations	Gastroenteritis viral	Mild	1.3% (0.3, 5.1)	0%	P=0.073, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.448
Infections and infestations	Gastroenteritis viral	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Infections and infestations	Gastroenteritis viral	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Otitis media acute		1.3% (0.3, 5.1)	2.4% (0.6, 9.0)	P=0.887, I <sup>2</sup> =0%	P=0.864, I <sup>2</sup> =0%							P=0.898
Infections and infestations	Otitis media acute	Mild	1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.887, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	1.120 (0.100, 12.587)	1.118 (0.102, 12.298) 0.927	0.001 (-0.028 - 0.031)	P=0.588, I <sup>2</sup> =0%	P=0.588, I <sup>2</sup> =0%	P=0.602, I <sup>2</sup> =0%	P=0.689
Infections and infestations	Otitis media acute	Moderate	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.815



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Infections and infestations	Otitis media acute	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Viral infection		1.3% (0.3, 5.1)	0%	P=0.073, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Viral infection	Mild	1.3% (0.3, 5.1)	0%	P=0.073, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
Infections and infestations	Viral infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Viral infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Varicella		1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.887, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.993
Infections and infestations	Varicella	Mild	0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.273, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	0.561 (0.034, 9.181)	0.566 (0.036, 8.846) 0.685	-0.005 (-0.032, 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.787
Infections and infestations	Varicella	Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006, 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Varicella	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Respiratory tract infection viral		1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.073 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%							P=0.677
Infections and infestations	Respiratory tract infection viral	Mild	1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.073 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%	1.091 (0.096, 12.448)	1.088 (0.102, 11.604) 0.944	0.001 (-0.028 - 0.030)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.677
Infections and infestations	Respiratory tract infection viral	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Respiratory tract infection viral	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Enteritis infectious		0%	2.4% (0.6, 9.0)	P=1.000, I <sup>2</sup> =0%	P=0.068, I <sup>2</sup> =0%							P=0.396
Infections and infestations	Enteritis infectious	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808
Infections and infestations	Enteritis infectious	Moderate	0%	2.4% (0.6, 9.0)	P=1.000, I <sup>2</sup> =0%	P=0.068, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.024 (-0.057 - 0.009)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.669

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Infections and infestations	Enteritis infectious	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Influenza		1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.887, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%							P=0.693
Infections and infestations	Influenza	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.815
Infections and infestations	Influenza	Moderate	1.3% (0.3, 5.1)	0%	P=0.887, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.031)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.738, I <sup>2</sup> =0%	P=0.460

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Influenza	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Otitis media		1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.120, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.670
Infections and infestations	Otitis media	Mild	1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.120, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	1.136 (0.100, 12.870)	1.133 (0.105, 12.159) 0.918	0.002 (-0.028 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.670
Infections and infestations	Otitis media	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Otitis media	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Periodontitis		2.0% (0.6, 6.0)	0%	P=0.056, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.420
Infections and infestations	Periodontitis	Mild	2.0% (0.6, 6.0)	0%	P=0.056, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.020 (-0.002 - 0.042)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.420
Infections and infestations	Periodontitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Periodontitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Infections and infestations	Herpangina		1.3% (0.3, 5.1)	0%	P=0.120, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.732
Infections and infestations	Herpangina	Mild	1.3% (0.3, 5.1)	0%	P=0.120, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732
Infections and infestations	Herpangina	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Herpangina	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Helminthic infection		0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.205, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%							P=0.905
Infections and infestations	Helminthic infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Helminthic infection	Moderate	0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.205, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	0.537 (0.033, 8.847)	0.544 (0.035, 8.450) 0.664	-0.005 (-0.032 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.905
Infections and infestations	Helminthic infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Pharyngoton sillitis		0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.205 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%							P=0.905
Infections and infestations	Pharyngoton sillitis	Mild	0%	1.2% (0.2, 8.0)	P=1.000 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.815
Infections and infestations	Pharyngoton sillitis	Moderate	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.635
Infections and infestations	Pharyngoton sillitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Hordeolum		0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.273 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%							P=0.900
Infections and infestations	Hordeolum	Mild	0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.273 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%	0.558 (0.035, 8.797)	0.558 (0.036, 8.683) 0.677	-0.005 (-0.032 - 0.021)	P=0.328, I <sup>2</sup> =0%	P=0.330, I <sup>2</sup> =0%	P=0.308, I <sup>2</sup> =396%	P=0.900
Infections and infestations	Hordeolum	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Hordeolum	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Pulpitis dental		1.3% (0.3, 5.1)	0%	P=0.887 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.460

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Infections and infestations	Pulpitis dental	Mild	1.3% (0.3, 5.1)	0%	P=0.887, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.031)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.738, I <sup>2</sup> =0%	P=0.460
Infections and infestations	Pulpitis dental	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Pulpitis dental	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Urinary tract infection		0%	2.4% (0.6, 9.0)	P=1.000, I <sup>2</sup> =0%	P=0.864, I <sup>2</sup> =0%							P=0.627

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Urinary tract infection	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.819
Infections and infestations	Urinary tract infection	Moderate	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.815
Infections and infestations	Urinary tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Viral upper respiratory tract infection		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%							P=0.524

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Viral upper respiratory tract infection	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.524
Infections and infestations	Viral upper respiratory tract infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Viral upper respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Laryngitis		0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.273 , I <sup>2</sup> =0%	P=0.279 , I <sup>2</sup> =0%							P=0.899
Infections and infestations	Laryngitis	Mild	0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.273 , I <sup>2</sup> =0%	P=0.279 , I <sup>2</sup> =0%	0.561 (0.034, 9.181)	0.566 (0.036, 8.846) 0.685	-0.005 (-0.032 - 0.021)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.899
Infections and infestations	Laryngitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Laryngitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Oral herpes		0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.273 , I <sup>2</sup> =0%	P=0.279 , I <sup>2</sup> =0%							P=0.899

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Infections and infestations	Oral herpes	Mild	0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.273, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	0.561 (0.034, 9.181)	0.566 (0.036, 8.846) 0.685	-0.005 (-0.032, 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.899
Infections and infestations	Oral herpes	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Oral herpes	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Hand-foot-and-mouth disease		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.890



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Hand-foot-and-mouth disease	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.890
Infections and infestations	Hand-foot-and-mouth disease	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Hand-foot-and-mouth disease	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Appendicitis		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Appendicitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Appendicitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Appendicitis	Severe	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Infections and infestations	Atypical pneumonia		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635
Infections and infestations	Atypical pneumonia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Atypical pneumonia	Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Infections and infestations	Atypical pneumonia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Conjunctivitis bacterial		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%							P=0.815
Infections and infestations	Conjunctivitis bacterial	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.815

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Conjunctivitis bacterial	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Conjunctivitis bacterial	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Cystitis		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635
Infections and infestations	Cystitis	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Cystitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Cystitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Enterobiasis		0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.635
Infections and infestations	Enterobiasis	Mild	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Enterobiasis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Enterobiasis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Infected bite		0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.635
Infections and infestations	Infected bite	Mild	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.635
Infections and infestations	Infected bite	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Infected bite	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Molluscum contagiosum		0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.635
Infections and infestations	Molluscum contagiosum	Mild	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Infections and infestations	Molluscum contagiosum	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Molluscum contagiosum	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Otitis externa		0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.635
Infections and infestations	Otitis externa	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Otitis externa	Moderate	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.635



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Otitis externa	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Tinea pedis		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635
Infections and infestations	Tinea pedis	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Infections and infestations	Tinea pedis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Tinea pedis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Tooth abscess		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635
Infections and infestations	Tooth abscess	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Infections and infestations	Tooth abscess	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Tooth abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Infections and infestations	Vulvitis		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635
Infections and infestations	Vulvitis	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Infections and infestations	Vulvitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Vulvitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Croup infectious		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.561
Infections and infestations	Croup infectious	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Croup infectious	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Croup infectious	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Eczema infected		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.808

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Eczema infected	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.808
Infections and infestations	Eczema infected	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Eczema infected	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Abscess limb		0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.633

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Abscess limb	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Infections and infestations	Abscess limb	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Abscess limb	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Bacterial infection		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.819
Infections and infestations	Bacterial infection	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.819

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Bacterial infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Bacterial infection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Chronic sinusitis		0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.633
Infections and infestations	Chronic sinusitis	Mild	0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Chronic sinusitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Chronic sinusitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Chronic tonsillitis		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633
Infections and infestations	Chronic tonsillitis	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Chronic tonsillitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Chronic tonsillitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Folliculitis		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633
Infections and infestations	Folliculitis	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Infections and infestations	Folliculitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Infections and infestations	Folliculitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Gastrointestinal bacterial infection		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633
Infections and infestations	Gastrointestinal bacterial infection	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Infections and infestations	Gastrointestinal bacterial infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Gastrointestinal bacterial infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Herpes virus infection		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.819
Infections and infestations	Herpes virus infection	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.819
Infections and infestations	Herpes virus infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Infections and infestations	Herpes virus infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Infectious mononucleosis		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.819
Infections and infestations	Infectious mononucleosis	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.819
Infections and infestations	Infectious mononucleosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Infectious mononucleosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Infections and infestations	Mumps		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633
Infections and infestations	Mumps	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Infections and infestations	Mumps	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Mumps	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Infections and infestations	Myringitis		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633
Infections and infestations	Myringitis	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Infections and infestations	Myringitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Myringitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Peritonsillar abscess		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.819
Infections and infestations	Peritonsillar abscess	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Peritonsillar abscess	Moderate	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.819
Infections and infestations	Peritonsillar abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Sinobronchitis		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.819

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Infections and infestations	Sinobronchitis	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.819
Infections and infestations	Sinobronchitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Sinobronchitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Subcutaneous abscess		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Infections and infestations	Subcutaneous abscess	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Subcutaneous abscess	Moderate	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Infections and infestations	Subcutaneous abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Tonsillitis bacterial		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Tonsillitis bacterial	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Tonsillitis bacterial	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Tonsillitis bacterial	Severe	0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Infections and infestations	Tracheitis		0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.633

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Infections and infestations	Tracheitis	Mild	0.7% (0.1, 4.5)	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Infections and infestations	Tracheitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Tracheitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Laryngitis viral		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Infections and infestations	Laryngitis viral	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Infections and infestations	Laryngitis viral	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Laryngitis viral	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Rotavirus infection		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Rotavirus infection	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Infections and infestations	Rotavirus infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Infections and infestations	Rotavirus infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations			30.5% (23.7, 38.3)	31.0% (22.0, 41.6)	P=0.000, I <sup>2</sup> =95.5%	P=0.000, I <sup>2</sup> =92%							P=0.886
Investigations		Mild	30.5% (23.7, 38.3)	31.0% (22.0, 41.6)	P=0.000, I <sup>2</sup> =95.5%	P=0.000, I <sup>2</sup> =92%	0.996 (0.515, 1.926)	0.998 (0.702, 1.418) 0.991	-0.001 (-0.109, 0.107)	P=0.208, I <sup>2</sup> =3683%	P=0.214, I <sup>2</sup> =3522%	P=0.128, I <sup>2</sup> =5674%	P=0.886
Investigations		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Insulin-like growth factor increased		17.9% (12.6, 24.8)	3.6% (1.2, 10.5)	P=0.000, I <sup>2</sup> =91.9%	P=0.059, I <sup>2</sup> =0%							P=0.490
Investigations	Insulin-like growth factor increased	Mild	17.9% (12.6, 24.8)	3.6% (1.2, 10.5)	P=0.000, I <sup>2</sup> =91.9%	P=0.059, I <sup>2</sup> =0%	6.848 (1.945, 24.111)	5.087 (1.623, 15.947) 0.005	0.145 (0.074 - 0.216)	P=0.561, I <sup>2</sup> =0%	P=0.675, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =9495%	P=0.490
Investigations	Insulin-like growth factor increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Insulin-like growth factor increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood glucose increased		9.3% (5.6, 15.0)	16.7% (10.1, 26.2)	P=0.000, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%							P=0.318
Investigations	Blood glucose increased	Mild	9.3% (5.6, 15.0)	16.7% (10.1, 26.2)	P=0.000, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =0%	0.478 (0.205, 1.118)	0.566 (0.296, 1.083)	-0.072 (-0.159, 0.015)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.318
Investigations	Blood glucose increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Blood glucose increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Low density lipoprotein increased		2.6% (1.0, 6.8)	4.8% (1.8, 12.0)	P=0.027, I <sup>2</sup> =0%	P=0.028, I <sup>2</sup> =0%							P=0.878
Investigations	Low density lipoprotein increased	Mild	2.6% (1.0, 6.8)	4.8% (1.8, 12.0)	P=0.027, I <sup>2</sup> =0%	P=0.028, I <sup>2</sup> =0%	0.544 (0.130, 2.285)	0.566 (0.148, 2.160) 0.405	-0.021 (-0.072, 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.878



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Investigation s	Low density lipoprotein increased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Investigation s	Low density lipoprotein increased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Investigation s	Blood alkaline phosphatase increased		1.3% (0.3, 5.1)	4.8% (1.8, 12.0)	P=0.120 , I <sup>2</sup> =0%	P=0.028 , I <sup>2</sup> =0%							P=0.489
Investigation s	Blood alkaline phosphatase increased	Mild	1.3% (0.3, 5.1)	4.8% (1.8, 12.0)	P=0.120 , I <sup>2</sup> =0%	P=0.028 , I <sup>2</sup> =0%	0.265 (0.047, 1.508)	0.283 (0.054, 1.488) 0.136	-0.034 (-0.083 - 0.015)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.489

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Blood alkaline phosphatase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood alkaline phosphatase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Eosinophil count increased		2.6% (1.0, 6.8)	1.2% (0.2, 8.0)	P=0.840, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.688
Investigations	Eosinophil count increased	Mild	2.6% (1.0, 6.8)	1.2% (0.2, 8.0)	P=0.840, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	2.267 (0.248, 20.698)	2.236 (0.251, 19.893) 0.47	0.015 (-0.020 - 0.049)	P=0.565, I <sup>2</sup> =0%	P=0.563, I <sup>2</sup> =0%	P=0.599, I <sup>2</sup> =0%	P=0.688

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Eosinophil count increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Eosinophil count increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood iron increased		1.3% (0.3, 5.1)	3.6% (1.2, 10.5)	P=0.120, I <sup>2</sup> =0%	P=0.700, I <sup>2</sup> =0%							P=0.967
Investigations	Blood iron increased	Mild	1.3% (0.3, 5.1)	3.6% (1.2, 10.5)	P=0.120, I <sup>2</sup> =0%	P=0.700, I <sup>2</sup> =0%	0.366 (0.060, 2.242)	0.376 (0.065, 2.181)	-0.022 (-0.066, 0.021)	P=0.548, I <sup>2</sup> =0%	P=0.543, I <sup>2</sup> =0%	P=0.749, I <sup>2</sup> =0%	P=0.967

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Blood iron increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood iron increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood phosphorus increased		2.6% (1.0, 6.8)	1.2% (0.2, 8.0)	P=0.027, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.443
Investigations	Blood phosphorus increased	Mild	2.6% (1.0, 6.8)	1.2% (0.2, 8.0)	P=0.027, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	2.329 (0.253, 21.472)	2.265 (0.261, 19.678) 0.459	0.015 (-0.019, 0.049)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.443

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Investigation s	Blood phosphorus increased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Investigation s	Blood phosphorus increased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Investigation s	Blood uric acid increased		1.3% (0.3, 5.1)	2.4% (0.6, 9.0)	P=0.120 , I <sup>2</sup> =0%	P=0.124 , I <sup>2</sup> =0%							P=0.782
Investigation s	Blood uric acid increased	Mild	1.3% (0.3, 5.1)	2.4% (0.6, 9.0)	P=0.120 , I <sup>2</sup> =0%	P=0.124 , I <sup>2</sup> =0%	0.556 (0.076, 4.079)	0.566 (0.082, 3.890) 0.563	-0.010 (-0.047 - 0.027)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.782
Investigation s	Blood uric acid increased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Blood uric acid increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Alanine aminotransferase increased		2.0% (0.6, 6.0)	1.2% (0.2, 8.0)	P=0.056, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.533
Investigations	Alanine aminotransferase increased	Mild	2.0% (0.6, 6.0)	1.2% (0.2, 8.0)	P=0.056, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	1.725 (0.174, 17.069)	1.699 (0.182, 15.873) 0.642	0.008 (-0.024 - 0.040)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.533
Investigations	Alanine aminotransferase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Alanine aminotransferase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Cortisol decreased		2.0% (0.6, 6.0)	1.2% (0.2, 8.0)	P=0.056, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.533
Investigations	Cortisol decreased	Mild	2.0% (0.6, 6.0)	1.2% (0.2, 8.0)	P=0.056, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	1.725 (0.174, 17.069)	1.699 (0.182, 15.873) 0.642	0.008 (-0.024 - 0.040)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.533
Investigations	Cortisol decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Cortisol decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood triglycerides increased		1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.120, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.670
Investigations	Blood triglycerides increased	Mild	1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.120, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	1.136 (0.100, 12.870)	1.133 (0.105, 12.159) 0.918	0.002 (-0.028 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.670
Investigations	Blood triglycerides increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood triglycerides increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Blood glucose abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.600
Investigations	Blood glucose abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.600
Investigations	Blood glucose abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood glucose abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Investigation s	Blood thyroid stimulating hormone increased		1.3% (0.3, 5.1)	0%	P=0.887, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.460
Investigation s	Blood thyroid stimulating hormone increased	Mild	1.3% (0.3, 5.1)	0%	P=0.887, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.031)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.738, I <sup>2</sup> =0%	P=0.460
Investigation s	Blood thyroid stimulating hormone increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Investigation s	Blood thyroid stimulating hormone increased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Investigation s	White blood cell count decreased		0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.893
Investigation s	White blood cell count decreased	Mild	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.007 (-0.006 - 0.019)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.893

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Investigation s	White blood cell count decreased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Investigation s	White blood cell count decreased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Investigation s	Aspartate aminotransfe rase increased		1.3% (0.3, 5.1)	0%	P=0.120 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.500
Investigation s	Aspartate aminotransfe rase increased	Mild	1.3% (0.3, 5.1)	0%	P=0.120 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.032)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.500

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Aspartate aminotransferase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Aspartate aminotransferase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood urea increased		0%	2.4% (0.6, 9.0)	P=1.000, I <sup>2</sup> =0%	P=0.124, I <sup>2</sup> =0%							P=0.674
Investigations	Blood urea increased	Mild	0%	2.4% (0.6, 9.0)	P=1.000, I <sup>2</sup> =0%	P=0.124, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.024 (-0.056 - 0.009)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.674

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Blood urea increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood urea increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Electrocardiogram T wave peaked		1.3% (0.3, 5.1)	0%	P=0.120, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.500
Investigations	Electrocardiogram T wave peaked	Mild	1.3% (0.3, 5.1)	0%	P=0.120, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.500
Investigations	Electrocardiogram T wave peaked	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Electrocardiogram T wave peaked	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Tri-iodothyronine free increased		0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.273, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.899
Investigations	Tri-iodothyronine free increased	Mild	0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.273, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	0.561 (0.034, 9.181)	0.566 (0.036, 8.846) 0.685	-0.005 (-0.032, 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.899
Investigations	Tri-iodothyronine free increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Tri-iodothyronine free increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood iron decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.644
Investigations	Blood iron decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.644
Investigations	Blood iron decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood iron decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Thyroxine decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.644
Investigations	Thyroxine decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.644
Investigations	Thyroxine decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Thyroxine decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Transaminases increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808
Investigations	Transaminases increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808
Investigations	Transaminases increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Transaminases increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood cholesterol increased		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Blood cholesterol increased	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Investigations	Blood cholesterol increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood cholesterol increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood lactate dehydrogenase increased		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.819

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Blood lactate dehydrogenase increased	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.819
Investigations	Blood lactate dehydrogenase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood lactate dehydrogenase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood potassium increased		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.819

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Blood potassium increased	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.819
Investigations	Blood potassium increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood potassium increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood pressure increased		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.819

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Blood pressure increased	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.819
Investigations	Blood pressure increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood pressure increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Electrocardiogram ST segment abnormal		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.819

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Electrocardiogram ST segment abnormal	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.819
Investigations	Electrocardiogram ST segment abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Electrocardiogram ST segment abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Electrocardiogram high voltage		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Electrocardiogram high voltage	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Investigations	Electrocardiogram high voltage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Electrocardiogram high voltage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Haemoglobin decreased		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.819
Investigations	Haemoglobin decreased	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.819



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Haemoglobin decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Haemoglobin decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Hepatic enzyme abnormal		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.819
Investigations	Hepatic enzyme abnormal	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.819

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Hepatic enzyme abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Hepatic enzyme abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Hepatic enzyme increased		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.819
Investigations	Hepatic enzyme increased	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.819

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Hepatic enzyme increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Hepatic enzyme increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Lipids increased		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.819
Investigations	Lipids increased	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.819
Investigations	Lipids increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Lipids increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Basophil count increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.821
Investigations	Basophil count increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.821
Investigations	Basophil count increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Basophil count increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Liver function test abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.620
Investigations	Liver function test abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.620
Investigations	Liver function test abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Liver function test abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Thyroid function test abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.620
Investigations	Thyroid function test abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.620

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Thyroid function test abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Thyroid function test abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood cortisol decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood cortisol decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Blood cortisol decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Blood cortisol decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Cortisol free urine decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Cortisol free urine decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Cortisol free urine decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Investigations	Cortisol free urine decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Thyroxine free decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Thyroxine free decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Thyroxine free decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Investigations	Thyroxine free decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders			31.1% (24.3, 38.9)	21.4% (13.9, 31.5)	P=0.262 , I <sup>2</sup> =19.6%	P=0.297 , I <sup>2</sup> =5%							P=0.567
Respiratory, thoracic and mediastinal disorders		Mild	27.8% (21.3, 35.5)	17.9% (11.1, 27.5)	P=0.029 , I <sup>2</sup> =78%	P=0.351 , I <sup>2</sup> =0%	1.804 (0.925, 3.517)	1.566 (0.929, 2.637) 0.092	0.101 (-0.007 - 0.209)	P=0.702, I <sup>2</sup> =0%	P=0.797, I <sup>2</sup> =0%	P=0.449, I <sup>2</sup> =0%	P=0.688
Respiratory, thoracic and mediastinal disorders		Moderate	3.3% (1.4, 7.7)	3.6% (1.2, 10.5)	P=0.004 , I <sup>2</sup> =0%	P=0.700 , I <sup>2</sup> =0%	0.913 (0.213, 3.917)	0.915 (0.221, 3.793) 0.903	-0.003 (-0.052 - 0.046)	P=0.088, I <sup>2</sup> =655%	P=0.091, I <sup>2</sup> =649%	P=0.077, I <sup>2</sup> =679%	P=0.956

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Respiratory, thoracic and mediastinal disorders	Cough		17.9% (12.6, 24.8)	13.1% (7.4, 22.1)	P=0.000, I <sup>2</sup> =90.1%	P=0.219, I <sup>2</sup> =28%							P=0.270

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Cough	Mild	17.2% (12.0, 24.1)	9.5% (4.8, 17.9)	P=0.000 , I <sup>2</sup> =90.9%	P=0.241 , I <sup>2</sup> =19%	2.060 (0.877, 4.839)	1.828 (0.879, 3.805) 0.107	0.079 (-0.007 - 0.164)	P=0.268, I <sup>2</sup> =1863%	P=0.320, I <sup>2</sup> =0%	P=0.026, I <sup>2</sup> =7988%	P=0.404
Respiratory, thoracic and mediastinal disorders	Cough	Moderate	0.7% (0.1, 4.5)	3.6% (1.2, 10.5)	P=0.205 , I <sup>2</sup> =0%	P=0.700 , I <sup>2</sup> =0%	0.179 (0.018, 1.762)	0.183 (0.019, 1.770) 0.142	-0.029 (-0.071 - 0.013)	P=0.405, I <sup>2</sup> =0%	P=0.403, I <sup>2</sup> =0%	P=0.451, I <sup>2</sup> =0%	P=0.768
Respiratory, thoracic and mediastinal disorders	Cough	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea		2.6% (1.0, 6.8)	6.0% (2.5, 13.5)	P=0.027, I <sup>2</sup> =0%	P=0.244, I <sup>2</sup> =11%							P=0.965
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Mild	2.6% (1.0, 6.8)	6.0% (2.5, 13.5)	P=0.027, I <sup>2</sup> =0%	P=0.244, I <sup>2</sup> =11%	0.430 (0.111, 1.671)	0.452 (0.127, 1.613) 0.221	-0.033 (-0.089, 0.024)	P=0.531, I <sup>2</sup> =0%	P=0.518, I <sup>2</sup> =0%	P=0.925, I <sup>2</sup> =0%	P=0.965
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic		3.3% (1.4, 7.7)	3.6% (1.2, 10.5)	P=0.817 , I <sup>2</sup> =0%	P=0.700 , I <sup>2</sup> =0%							P=0.639
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Mild	3.3% (1.4, 7.7)	3.6% (1.2, 10.5)	P=0.817 , I <sup>2</sup> =0%	P=0.700 , I <sup>2</sup> =0%	0.927 (0.216, 3.984)	0.930 (0.228, 3.795) 0.919	-0.003 (-0.051 - 0.046)	P=0.869, I <sup>2</sup> =0%	P=0.869, I <sup>2</sup> =0%	P=0.856, I <sup>2</sup> =0%	P=0.639

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Respiratory, thoracic and mediastinal disorders	Asthma		2.6% (1.0, 6.8)	2.4% (0.6, 9.0)	P=0.840, I <sup>2</sup> =0%	P=0.864, I <sup>2</sup> =0%							P=0.575

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Asthma	Mild	2.0% (0.6, 6.0)	1.2% (0.2, 8.0)	P=0.677, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	1.701 (0.173, 16.749)	1.684 (0.177, 15.990) 0.65	0.008 (-0.024 - 0.040)	P=0.744, I <sup>2</sup> =0%	P=0.743, I <sup>2</sup> =0%	P=0.844, I <sup>2</sup> =0%	P=0.527
Respiratory, thoracic and mediastinal disorders	Asthma	Moderate	0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.205, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	0.537 (0.033, 8.847)	0.544 (0.035, 8.450) 0.664	-0.005 (-0.032 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.905



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Asthma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Respiratory, thoracic and mediastinal disorders	Nasal congestion		1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.073 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%							P=0.376
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Mild	0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.205 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%	0.537 (0.033, 8.847)	0.544 (0.035, 8.450)	-0.005 (-0.032 - 0.021)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.586

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Respiratory, thoracic and mediastinal disorders	Epistaxis		1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.073, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%							P=0.677

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Epistaxis	Mild	1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.073, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	1.091 (0.096, 12.448)	1.088 (0.102, 11.604) 0.944	0.001 (-0.028 - 0.030)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.677
Respiratory, thoracic and mediastinal disorders	Epistaxis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Respiratory, thoracic and mediastinal disorders	Epistaxis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Respiratory disorder		1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.073, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%							P=0.677
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Mild	0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.205, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	0.537 (0.033, 8.847)	0.544 (0.035, 8.450) 0.664	-0.005 (-0.032, 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.905
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006, 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Respiratory, thoracic and mediastinal disorders	Sinus congestion		2.0% (0.6, 6.0)	0%	P=0.027, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.422

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Mild	1.3% (0.3, 5.1)	0%	P=0.073, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.503
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Allergic cough		1.3% (0.3, 5.1)	0%	P=0.887, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.460
Respiratory, thoracic and mediastinal disorders	Allergic cough	Mild	1.3% (0.3, 5.1)	0%	P=0.887, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.031)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.738, I <sup>2</sup> =0%	P=0.460
Respiratory, thoracic and mediastinal disorders	Allergic cough	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Allergic cough	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome		1.3% (0.3, 5.1)	0%	P=0.887 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.460
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Mild	0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Respiratory, thoracic and mediastinal disorders	Wheezing		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Wheezing	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808
Respiratory, thoracic and mediastinal disorders	Wheezing	Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Wheezing	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Respiratory, thoracic and mediastinal disorders	Laryngospasm		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Moderate	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.635
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Nasal obstruction		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Respiratory, thoracic and mediastinal disorders	Productive cough		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Productive cough	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Respiratory, thoracic and mediastinal disorders	Productive cough	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Respiratory, thoracic and mediastinal disorders	Productive cough	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
General disorders and administrati on site conditions			18.5% (13.1, 25.5)	22.6% (14.9, 32.8)	P=0.497 , I <sup>2</sup> =0%	P=0.470 , I <sup>2</sup> =0%							P=0.308
General disorders and administrati on site conditions		Mild	14.6% (9.8, 21.1)	21.4% (13.9, 31.5)	P=0.172 , I <sup>2</sup> =43.7 %	P=0.618 , I <sup>2</sup> =0%	0.627 (0.314, 1.252)	0.683 (0.390, 1.196) 0.182	-0.068 (-0.172 - 0.036)	P=0.600, I <sup>2</sup> =0%	P=0.564, I <sup>2</sup> =0%	P=0.753, I <sup>2</sup> =0%	P=0.225

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions		Moderate	4.0% (1.8, 8.6)	1.2% (0.2, 8.0)	P=0.276, I <sup>2</sup> =9.8%	P=0.279, I <sup>2</sup> =0%	3.398 (0.405, 28.534)	3.340 (0.402, 27.771) 0.264	0.028 (-0.011 - 0.067)	P=0.352, I <sup>2</sup> =0%	P=0.351, I <sup>2</sup> =0%	P=0.248, I <sup>2</sup> =2515%	P=0.361
General disorders and administration site conditions		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions	Pyrexia		15.9% (10.9, 22.6)	14.3% (8.3, 23.5)	P=0.932, I <sup>2</sup> =0%	P=0.857, I <sup>2</sup> =0%							P=0.617
General disorders and administration site conditions	Pyrexia	Mild	12.6% (8.2, 18.9)	13.1% (7.4, 22.1)	P=0.440, I <sup>2</sup> =0%	P=0.920, I <sup>2</sup> =0%	0.957 (0.432, 2.120)	0.963 (0.482, 1.924) 0.914	-0.005 (-0.094 - 0.085)	P=0.583, I <sup>2</sup> =0%	P=0.581, I <sup>2</sup> =0%	P=0.591, I <sup>2</sup> =0%	P=0.512

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
General disorders and administrati on site conditions	Pyrexia	Moderate	3.3% (1.4, 7.7)	1.2% (0.2, 8.0)	P=0.103 , I <sup>2</sup> =52.1 %	P=0.279 , I <sup>2</sup> =0%	2.796 (0.325, 24.045)	2.774 (0.322, 23.930) 0.353	0.021 (-0.016 - 0.058)	P=0.23 0, I <sup>2</sup> =306 4%	P=0.23 0, I <sup>2</sup> =304 7%	P=0.12 6, I <sup>2</sup> =573 5%	P=0.460
General disorders and administrati on site conditions	Pyrexia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
General disorders and administrati on site conditions	Injection site pruritus		1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.120 , I <sup>2</sup> =0%	P=0.279 , I <sup>2</sup> =0%							P=0.670



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions	Injection site pruritus	Mild	1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.120, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	1.136 (0.100, 12.870)	1.133 (0.105, 12.159) 0.918	0.002 (-0.028 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.670
General disorders and administration site conditions	Injection site pruritus	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
General disorders and administrati on site conditions	Injection site pruritus	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
General disorders and administrati on site conditions	Injection site pain		1.3% (0.3, 5.1)	0%	P=0.120 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.732

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
General disorders and administrati on site conditions	Injection site pain	Mild	1.3% (0.3, 5.1)	0%	P=0.120 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732
General disorders and administrati on site conditions	Injection site pain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
General disorders and administrati on site conditions	Injection site pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions	Injection site swelling		0%	2.4% (0.6, 9.0)	P=1.000, I <sup>2</sup> =0%	P=0.864, I <sup>2</sup> =0%							P=0.627
General disorders and administration site conditions	Injection site swelling	Mild	0%	2.4% (0.6, 9.0)	P=1.000, I <sup>2</sup> =0%	P=0.864, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.024 (-0.056 - 0.009)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.796, I <sup>2</sup> =0%	P=0.627

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions	Injection site swelling	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
General disorders and administration site conditions	Injection site swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
General disorders and administrati on site conditions	Injection site erythema		0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.273 , I <sup>2</sup> =0%	P=0.279 , I <sup>2</sup> =0%							P=0.899
General disorders and administrati on site conditions	Injection site erythema	Mild	0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.273 , I <sup>2</sup> =0%	P=0.279 , I <sup>2</sup> =0%	0.561 (0.034, 9.181)	0.566 (0.036, 8.846) 0.685	-0.005 (-0.032 - 0.021)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.899
General disorders and administrati on site conditions	Injection site erythema	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
General disorders and administrati on site conditions	Injection site erythema	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
General disorders and administrati on site conditions	Injection site reaction		1.3% (0.3, 5.1)	0%	P=0.120 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.500

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions	Injection site reaction	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
General disorders and administration site conditions	Injection site reaction	Moderate	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
General disorders and administrati on site conditions	Injection site reaction	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
General disorders and administrati on site conditions	Injection site urticaria		0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.635
General disorders and administrati on site conditions	Injection site urticaria	Mild	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions	Injection site urticaria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
General disorders and administration site conditions	Injection site urticaria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions	Medical device discomfort		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%							P=0.815
General disorders and administration site conditions	Medical device discomfort	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.815

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
General disorders and administrati on site conditions	Medical device discomfort	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
General disorders and administrati on site conditions	Medical device discomfort	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
General disorders and administrati on site conditions	Vaccination site pain		0%	1.2% (0.2, 8.0)	P=1.000 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%							P=0.815

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
General disorders and administrati on site conditions	Vaccination site pain	Mild	0%	1.2% (0.2, 8.0)	P=1.000 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.815
General disorders and administrati on site conditions	Vaccination site pain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions	Vaccination site pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
General disorders and administration site conditions	Fatigue		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions	Fatigue	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808
General disorders and administration site conditions	Fatigue	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
General disorders and administration site conditions	Fatigue	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions	Gait disturbance		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808
General disorders and administration site conditions	Gait disturbance	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions	Gait disturbance	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
General disorders and administration site conditions	Gait disturbance	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions	Injection site atrophy		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808
General disorders and administration site conditions	Injection site atrophy	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808
General disorders and administration site conditions	Injection site atrophy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions	Injection site atrophy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
General disorders and administration site conditions	Injection site bruising		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.819

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions	Injection site bruising	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.819
General disorders and administration site conditions	Injection site bruising	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
General disorders and administrati on site conditions	Injection site bruising	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
General disorders and administrati on site conditions	Injection site haemorrhage		0%	1.2% (0.2, 8.0)	P=1.000 , I <sup>2</sup> =0%	P=0.279 , I <sup>2</sup> =0%							P=0.819
General disorders and administrati on site conditions	Injection site haemorrhage	Mild	0%	1.2% (0.2, 8.0)	P=1.000 , I <sup>2</sup> =0%	P=0.279 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.819

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions	Injection site haemorrhage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
General disorders and administration site conditions	Injection site haemorrhage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
General disorders and administrati on site conditions	Pain		0%	1.2% (0.2, 8.0)	P=1.000 , I <sup>2</sup> =0%	P=0.279 , I <sup>2</sup> =0%							P=0.819
General disorders and administrati on site conditions	Pain	Mild	0%	1.2% (0.2, 8.0)	P=1.000 , I <sup>2</sup> =0%	P=0.279 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.819

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
General disorders and administrati on site conditions	Pain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
General disorders and administrati on site conditions	Pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
General disorders and administrati on site conditions	Peripheral swelling		0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.633



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions	Peripheral swelling	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
General disorders and administration site conditions	Peripheral swelling	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions	Peripheral swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
General disorders and administration site conditions	Face oedema		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions	Face oedema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
General disorders and administration site conditions	Face oedema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
General disorders and administration site conditions	Face oedema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions	Influenza like illness		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
General disorders and administration site conditions	Influenza like illness	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
General disorders and administration site conditions	Influenza like illness	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
General disorders and administration site conditions	Influenza like illness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Gastrointestinal disorders			21.9% (16.0, 29.1)	17.9% (11.1, 27.5)	P=0.215, I <sup>2</sup> =34.6%	P=0.727, I <sup>2</sup> =0%							P=0.421

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Gastrointesti nal disorders		Mild	21.2% (15.4, 28.4)	15.5% (9.2, 24.9)	P=0.301 , I <sup>2</sup> =6.2%	P=0.287 , I <sup>2</sup> =7%	1.463 (0.722, 2.962)	1.369 (0.758, 2.472) 0.297	0.057 (-0.045 - 0.159)	P=0.15 3, I <sup>2</sup> =510 3%	P=0.15 9, I <sup>2</sup> =496 7%	P=0.13 4, I <sup>2</sup> =555 2%	P=0.377
Gastrointesti nal disorders		Moderate	0.7% (0.1, 4.5)	2.4% (0.6, 9.0)	P=0.205 , I <sup>2</sup> =0%	P=0.068 , I <sup>2</sup> =0%	0.261 (0.023, 2.982)	0.272 (0.026, 2.901) 0.281	-0.017 (-0.052 - 0.017)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.863
Gastrointesti nal disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Gastrointesti nal disorders	Diarrhoea		6.6% (3.6, 11.9)	8.3% (4.0, 16.5)	P=0.744 , I <sup>2</sup> =0%	P=0.947 , I <sup>2</sup> =0%							P=0.954

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Gastrointesti nal disorders	Diarrhoea	Mild	6.6% (3.6, 11.9)	8.3% (4.0, 16.5)	P=0.744 , I <sup>2</sup> =0%	P=0.947 , I <sup>2</sup> =0%	0.779 (0.285, 2.129)	0.794 (0.314, 2.010) 0.626	-0.017 (-0.088 - 0.054)	P=0.79 6, I <sup>2</sup> =0%	P=0.79 5, I <sup>2</sup> =0%	P=0.81 3, I <sup>2</sup> =0%	P=0.954
Gastrointesti nal disorders	Diarrhoea	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Gastrointesti nal disorders	Diarrhoea	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Gastrointesti nal disorders	Vomiting		5.3% (2.7, 10.2)	3.6% (1.2, 10.5)	P=0.010 , I <sup>2</sup> =76.7 %	P=0.024 , I <sup>2</sup> =0%							P=0.768

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Gastrointestinal disorders	Vomiting	Mild	5.3% (2.7, 10.2)	2.4% (0.6, 9.0)	P=0.010, I <sup>2</sup> =76.7%	P=0.068, I <sup>2</sup> =0%	2.319 (0.469, 11.480)	2.184 (0.486, 9.806) 0.308	0.028 (-0.019, 0.076)	P=0.803, I <sup>2</sup> =0%	P=0.817, I <sup>2</sup> =0%	P=0.275, I <sup>2</sup> =1602%	P=0.596
Gastrointestinal disorders	Vomiting	Moderate	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035, 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.815
Gastrointestinal disorders	Vomiting	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Gastrointestinal disorders	Nausea		3.3% (1.4, 7.7)	2.4% (0.6, 9.0)	P=0.103, I <sup>2</sup> =52.1%	P=0.068, I <sup>2</sup> =0%							P=0.529



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Gastrointesti nal disorders	Nausea	Mild	2.6% (1.0, 6.8)	1.2% (0.2, 8.0)	P=0.217 , I <sup>2</sup> =23.2 %	P=0.198 , I <sup>2</sup> =0%	2.246 (0.244, 20.674)	2.191 (0.253, 18.981) 0.477	0.014 (-0.020 - 0.049)	P=0.76 2, I <sup>2</sup> =0%	P=0.76 4, I <sup>2</sup> =0%	P=0.73 3, I <sup>2</sup> =0%	P=0.431
Gastrointesti nal disorders	Nausea	Moderate	0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.205 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%	0.537 (0.033, 8.847)	0.544 (0.035, 8.450) 0.664	-0.005 (-0.032 - 0.021)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.905
Gastrointesti nal disorders	Nausea	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Gastrointesti nal disorders	Abdominal pain upper		2.6% (1.0, 6.8)	1.2% (0.2, 8.0)	P=0.217 , I <sup>2</sup> =23.2 %	P=0.198 , I <sup>2</sup> =0%							P=0.666

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Gastrointesti nal disorders	Abdominal pain upper	Mild	2.6% (1.0, 6.8)	1.2% (0.2, 8.0)	P=0.217 , I <sup>2</sup> =23.2 %	P=0.198 , I <sup>2</sup> =0%	2.246 (0.244, 20.674)	2.191 (0.253, 18.981) 0.477	0.014 (-0.020 - 0.049)	P=0.76 2, I <sup>2</sup> =0%	P=0.76 4, I <sup>2</sup> =0%	P=0.73 3, I <sup>2</sup> =0%	P=0.666
Gastrointesti nal disorders	Abdominal pain upper	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Gastrointesti nal disorders	Abdominal pain upper	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Gastrointesti nal disorders	Abdominal pain		2.0% (0.6, 6.0)	0%	P=0.446 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.306
Gastrointesti nal disorders	Abdominal pain	Mild	1.3% (0.3, 5.1)	0%	P=0.887 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.031)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.73 8, I <sup>2</sup> =0%	P=0.400

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Gastrointesti nal disorders	Abdominal pain	Moderate	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.635
Gastrointesti nal disorders	Abdominal pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Gastrointesti nal disorders	Dyspepsia		2.0% (0.6, 6.0)	2.4% (0.6, 9.0)	P=0.677 , I <sup>2</sup> =0%	P=0.124 , I <sup>2</sup> =0%							P=0.745
Gastrointesti nal disorders	Dyspepsia	Mild	2.0% (0.6, 6.0)	2.4% (0.6, 9.0)	P=0.677 , I <sup>2</sup> =0%	P=0.124 , I <sup>2</sup> =0%	0.838 (0.136, 5.153)	0.842 (0.143, 4.948) 0.849	-0.004 (-0.043 - 0.036)	P=0.56 1, I <sup>2</sup> =0%	P=0.56 2, I <sup>2</sup> =0%	P=0.51 6, I <sup>2</sup> =0%	P=0.745

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Gastrointestinal disorders	Dyspepsia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Gastrointestinal disorders	Dyspepsia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Gastrointestinal disorders	Constipation		2.0% (0.6, 6.0)	1.2% (0.2, 8.0)	P=0.027, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.662
Gastrointestinal disorders	Constipation	Mild	1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.073, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	1.104 (0.099, 12.299)	1.104 (0.098, 12.441) 0.936	0.001 (-0.028 - 0.031)	P=0.215, I <sup>2</sup> =3495%	P=0.217, I <sup>2</sup> =3448%	P=0.211, I <sup>2</sup> =3616%	P=0.754

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Gastrointesti nal disorders	Constipation	Moderate	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.635
Gastrointesti nal disorders	Constipation	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Gastrointesti nal disorders	Toothache		1.3% (0.3, 5.1)	0%	P=0.887 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.227
Gastrointesti nal disorders	Toothache	Mild	1.3% (0.3, 5.1)	0%	P=0.887 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.031)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.73 8, I <sup>2</sup> =0%	P=0.227

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Gastrointestinal disorders	Toothache	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Gastrointestinal disorders	Toothache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Gastrointestinal disorders	Abdominal discomfort		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Gastrointestinal disorders	Abdominal discomfort	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Gastrointestinal disorders	Abdominal discomfort	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Gastrointestinal disorders	Abdominal discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Gastrointestinal disorders	Enteritis		0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.273, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.899
Gastrointestinal disorders	Enteritis	Mild	0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.273, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	0.561 (0.034, 9.181)	0.566 (0.036, 8.846) 0.685	-0.005 (-0.032, 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.899
Gastrointestinal disorders	Enteritis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Gastrointestinal disorders	Enteritis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Gastrointestinal disorders	Gastrointestinal disorder		1.3% (0.3, 5.1)	0%	P=0.120, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.500
Gastrointestinal disorders	Gastrointestinal disorder	Mild	1.3% (0.3, 5.1)	0%	P=0.120, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.500
Gastrointestinal disorders	Gastrointestinal disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Gastrointestinal disorders	Gastrointestinal disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Gastrointestinal disorders	Aphthous ulcer		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%							P=0.815
Gastrointestinal disorders	Aphthous ulcer	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.815
Gastrointestinal disorders	Aphthous ulcer	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Gastrointesti nal disorders	Aphthous ulcer	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Gastrointesti nal disorders	Gastric disorder		0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.635
Gastrointesti nal disorders	Gastric disorder	Mild	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.635
Gastrointesti nal disorders	Gastric disorder	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Gastrointesti nal disorders	Gastric disorder	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Gastrointesti nal disorders	Lip swelling		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.808
Gastrointesti nal disorders	Lip swelling	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.808
Gastrointesti nal disorders	Lip swelling	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Gastrointesti nal disorders	Lip swelling	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Gastrointestinal disorders	Abdominal distension		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633
Gastrointestinal disorders	Abdominal distension	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Gastrointestinal disorders	Abdominal distension	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Gastrointestinal disorders	Abdominal distension	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Gastrointestinal disorders	Noninfective gingivitis		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.819

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Gastrointestinal disorders	Noninfective gingivitis	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.819
Gastrointestinal disorders	Noninfective gingivitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Gastrointestinal disorders	Noninfective gingivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Gastrointestinal disorders	Gastrointestinal motility disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Gastrointestinal disorders	Gastrointestinal motility disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Gastrointestinal disorders	Gastrointestinal motility disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Gastrointestinal disorders	Gastrointestinal motility disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Nervous system disorders			7.9% (4.6, 13.5)	14.3% (8.3, 23.5)	P=0.004, I <sup>2</sup> =83.3%	P=0.088, I <sup>2</sup> =63%							P=0.689

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Nervous system disorders		Mild	6.0% (3.1, 11.1)	11.9% (6.5, 20.7)	P=0.039 , I <sup>2</sup> =71.5%	P=0.281 , I <sup>2</sup> =12%	0.456 (0.175, 1.188)	0.495 (0.211, 1.162) 0.106	-0.060 (-0.138 - 0.018)	P=0.452, I <sup>2</sup> =0%	P=0.414, I <sup>2</sup> =0%	P=0.982, I <sup>2</sup> =0%	P=0.729
Nervous system disorders		Moderate	2.0% (0.6, 6.0)	2.4% (0.6, 9.0)	P=0.027 , I <sup>2</sup> =0%	P=0.068 , I <sup>2</sup> =0%	0.808 (0.129, 5.064)	0.816 (0.143, 4.668) 0.819	-0.004 (-0.043 - 0.035)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.925
Nervous system disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Nervous system disorders	Headache		6.0% (3.1, 11.1)	10.7% (5.7, 19.3)	P=0.000 , I <sup>2</sup> =0%	P=0.148 , I <sup>2</sup> =49%							P=0.790

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Nervous system disorders	Headache	Mild	4.0% (1.8, 8.6)	8.3% (4.0, 16.5)	P=0.002, I <sup>2</sup> =0%	P=0.468, I <sup>2</sup> =0%	0.441 (0.140, 1.386)	0.469 (0.164, 1.344) 0.159	-0.044 (-0.111, 0.022)	P=0.148, I <sup>2</sup> =5217%	P=0.140, I <sup>2</sup> =5402%	P=0.477, I <sup>2</sup> =0%	P=0.832
Nervous system disorders	Headache	Moderate	2.0% (0.6, 6.0)	2.4% (0.6, 9.0)	P=0.027, I <sup>2</sup> =0%	P=0.068, I <sup>2</sup> =0%	0.808 (0.129, 5.064)	0.816 (0.143, 4.668) 0.819	-0.004 (-0.043, 0.035)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.925
Nervous system disorders	Headache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Nervous system disorders	Dizziness		2.6% (1.0, 6.8)	2.4% (0.6, 9.0)	P=0.840, I <sup>2</sup> =0%	P=0.864, I <sup>2</sup> =0%							P=0.575



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Nervous system disorders	Dizziness	Mild	2.6% (1.0, 6.8)	2.4% (0.6, 9.0)	P=0.840 , I <sup>2</sup> =0%	P=0.864 , I <sup>2</sup> =0%	1.113 (0.200, 6.211)	1.110 (0.208, 5.933) 0.903	0.003 (-0.039 - 0.044)	P=0.982, I <sup>2</sup> =0%	P=0.981, I <sup>2</sup> =0%	P=0.992, I <sup>2</sup> =0%	P=0.575
Nervous system disorders	Dizziness	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Nervous system disorders	Dizziness	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Nervous system disorders	Post-traumatic headache		0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.205 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%							P=0.905
Nervous system disorders	Post-traumatic headache	Mild	0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.205 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%	0.537 (0.033, 8.847)	0.544 (0.035, 8.450) 0.664	-0.005 (-0.032 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.905

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Nervous system disorders	Post-traumat ic headache	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Nervous system disorders	Post-traumat ic headache	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Nervous system disorders	Migraine		0%	1.2% (0.2, 8.0)	P=1.000 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%							P=0.815
Nervous system disorders	Migraine	Mild	0%	1.2% (0.2, 8.0)	P=1.000 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.815

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Nervous system disorders	Migraine	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Nervous system disorders	Migraine	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Nervous system disorders	Tremor		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808
Nervous system disorders	Tremor	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Nervous system disorders	Tremor	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Nervous system disorders	Tremor	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications			10.6% (6.6, 16.6)	6.0% (2.5, 13.5)	P=0.043 , I <sup>2</sup> =73.6%	P=0.460 , I <sup>2</sup> =0%							P=0.999
Injury, poisoning and procedural complications		Mild	7.3% (4.1, 12.7)	4.8% (1.8, 12.0)	P=0.198 , I <sup>2</sup> =37%	P=0.807 , I <sup>2</sup> =0%	1.564 (0.481, 5.082)	1.521 (0.500, 4.629) 0.46	0.025 (-0.037 - 0.086)	P=0.640, I <sup>2</sup> =0%	P=0.650, I <sup>2</sup> =0%	P=0.493, I <sup>2</sup> =0%	P=0.927

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications		Moderate	3.3% (1.4, 7.7)	1.2% (0.2, 8.0)	P=0.103 , I <sup>2</sup> =52.1 %	P=0.198 , I <sup>2</sup> =0%	2.843 (0.322, 25.143)	2.735 (0.330, 22.637) 0.351	0.021 (-0.016 - 0.057)	P=0.714, I <sup>2</sup> =0%	P=0.723, I <sup>2</sup> =0%	P=0.479, I <sup>2</sup> =0%	P=0.589
Injury, poisoning and procedural complications		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Head injury		1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.887 , I <sup>2</sup> =0%	P=0.279 , I <sup>2</sup> =0%							P=0.689

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Head injury	Mild	1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.887, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	1.120 (0.100, 12.587)	1.118 (0.102, 12.298) 0.927	0.001 (-0.028 - 0.031)	P=0.588, I <sup>2</sup> =0%	P=0.588, I <sup>2</sup> =0%	P=0.602, I <sup>2</sup> =0%	P=0.689
Injury, poisoning and procedural complications	Head injury	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Head injury	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Arthropod bite		0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.205 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%							P=0.905
Injury, poisoning and procedural complications	Arthropod bite	Mild	0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.205 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%	0.537 (0.033, 8.847)	0.544 (0.035, 8.450) 0.664	-0.005 (-0.032 - 0.021)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.905

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Arthropod bite	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Arthropod bite	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Post-traumatic pain		0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.205 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%							P=0.905



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Injury, poisoning and procedural complications	Post-traumatic pain	Mild	0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.205, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	0.537 (0.033, 8.847)	0.544 (0.035, 8.450) 0.664	-0.005 (-0.032, 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.905
Injury, poisoning and procedural complications	Post-traumatic pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Post-traumatic pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Contusion		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Contusion	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Injury, poisoning and procedural complications	Contusion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Contusion	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Ligament sprain		0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.893

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Ligament sprain	Mild	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.893
Injury, poisoning and procedural complications	Ligament sprain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Ligament sprain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Injury, poisoning and procedural complications	Skin laceration		1.3% (0.3, 5.1)	0%	P=0.120, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.500
Injury, poisoning and procedural complications	Skin laceration	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Injury, poisoning and procedural complications	Skin laceration	Moderate	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Skin laceration	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Animal bite		0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.635
Injury, poisoning and procedural complications	Animal bite	Mild	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Animal bite	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Animal bite	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Ankle fracture		0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Ankle fracture	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Ankle fracture	Moderate	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Ankle fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Burns second degree		0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.635
Injury, poisoning and procedural complications	Burns second degree	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Burns second degree	Moderate	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Injury, poisoning and procedural complications	Burns second degree	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Face injury		0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Face injury	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Face injury	Moderate	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.635
Injury, poisoning and procedural complications	Face injury	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Fall		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635
Injury, poisoning and procedural complications	Fall	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Injury, poisoning and procedural complications	Fall	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Injury, poisoning and procedural complications	Fall	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Laceration		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Injury, poisoning and procedural complications	Laceration	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Injury, poisoning and procedural complications	Laceration	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Laceration	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Meniscus injury		0%	1.2% (0.2, 8.0)	P=1.000 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%							P=0.815
Injury, poisoning and procedural complications	Meniscus injury	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Meniscus injury	Moderate	0%	1.2% (0.2, 8.0)	P=1.000 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.815

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Meniscus injury	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Muscle strain		0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.635
Injury, poisoning and procedural complications	Muscle strain	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Injury, poisoning and procedural complications	Muscle strain	Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Injury, poisoning and procedural complications	Muscle strain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Thermal burn		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%							P=0.815

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Thermal burn	Mild	0%	1.2% (0.2, 8.0)	P=1.000 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.815
Injury, poisoning and procedural complications	Thermal burn	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Thermal burn	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Wrist fracture		0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.635
Injury, poisoning and procedural complications	Wrist fracture	Mild	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Wrist fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Wrist fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Radius fracture		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.808

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Radius fracture	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.808
Injury, poisoning and procedural complications	Radius fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Radius fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Animal scratch		0%	1.2% (0.2, 8.0)	P=1.000 , I <sup>2</sup> =0%	P=0.279 , I <sup>2</sup> =0%							P=0.819
Injury, poisoning and procedural complications	Animal scratch	Mild	0%	1.2% (0.2, 8.0)	P=1.000 , I <sup>2</sup> =0%	P=0.279 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.819
Injury, poisoning and procedural complications	Animal scratch	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Animal scratch	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Eye injury		0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.633

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Injury, poisoning and procedural complications	Eye injury	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Injury, poisoning and procedural complications	Eye injury	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Eye injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Joint injury		0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.633
Injury, poisoning and procedural complications	Joint injury	Mild	0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.633
Injury, poisoning and procedural complications	Joint injury	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Joint injury	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Burns first degree		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Burns first degree	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Burns first degree	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Burns first degree	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Concussion		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Injury, poisoning and procedural complications	Concussion	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Concussion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Concussion	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Upper limb fracture		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Upper limb fracture	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Injury, poisoning and procedural complications	Upper limb fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Injury, poisoning and procedural complications	Upper limb fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders			9.9% (6.1, 15.8)	3.6% (1.2, 10.5)	P=0.894 , I <sup>2</sup> =0%	P=0.422 , I <sup>2</sup> =0%							P=0.170

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Skin and subcutaneous tissue disorders		Mild	9.3% (5.6, 15.0)	3.6% (1.2, 10.5)	P=0.863, I <sup>2</sup> =0%	P=0.422, I <sup>2</sup> =0%	2.748 (0.768, 9.839)	2.589 (0.767, 8.736) 0.125	0.057 (-0.004 - 0.118)	P=0.431, I <sup>2</sup> =0%	P=0.428, I <sup>2</sup> =0%	P=0.515, I <sup>2</sup> =0%	P=0.388
Skin and subcutaneous tissue disorders		Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.387
Skin and subcutaneous tissue disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Rash		2.0% (0.6, 6.0)	1.2% (0.2, 8.0)	P=0.027, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%							P=0.269

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Skin and subcutaneous tissue disorders	Rash	Mild	2.0% (0.6, 6.0)	1.2% (0.2, 8.0)	P=0.027, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	1.662 (0.167, 16.564)	1.632 (0.176, 15.142) 0.666	0.008 (-0.024 - 0.039)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.269
Skin and subcutaneous tissue disorders	Rash	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Rash	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Skin and subcutaneous tissue disorders	Dermatitis allergic		1.3% (0.3, 5.1)	2.4% (0.6, 9.0)	P=0.120, I <sup>2</sup> =0%	P=0.864, I <sup>2</sup> =0%							P=0.869
Skin and subcutaneous tissue disorders	Dermatitis allergic	Mild	1.3% (0.3, 5.1)	2.4% (0.6, 9.0)	P=0.120, I <sup>2</sup> =0%	P=0.864, I <sup>2</sup> =0%	0.557 (0.077, 4.008)	0.562 (0.081, 3.888)	-0.010 (-0.048 - 0.027)	P=0.367, I <sup>2</sup> =0%	P=0.368, I <sup>2</sup> =0%	P=0.412, I <sup>2</sup> =0%	P=0.869
Skin and subcutaneous tissue disorders	Dermatitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Dermatitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Skin and subcutaneous tissue disorders	Urticaria		2.6% (1.0, 6.8)	0%	P=0.401, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.312
Skin and subcutaneous tissue disorders	Urticaria	Mild	2.6% (1.0, 6.8)	0%	P=0.401, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (0.001 - 0.052)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.466, I <sup>2</sup> =0%	P=0.312
Skin and subcutaneous tissue disorders	Urticaria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Skin and subcutaneous tissue disorders	Urticaria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Eczema		2.0% (0.6, 6.0)	0%	P=0.677, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.368
Skin and subcutaneous tissue disorders	Eczema	Mild	1.3% (0.3, 5.1)	0%	P=0.120, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.013 (-0.005 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.500
Skin and subcutaneous tissue disorders	Eczema	Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Skin and subcutaneous tissue disorders	Eczema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Dermatitis contact		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.905
Skin and subcutaneous tissue disorders	Dermatitis contact	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.905

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Skin and subcutaneous tissue disorders	Dermatitis contact	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Dermatitis contact	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Urticaria papular		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.890
Skin and subcutaneous tissue disorders	Urticaria papular	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.890

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Skin and subcutaneous tissue disorders	Urticaria papular	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Urticaria papular	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Cafe au lait spots		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Skin and subcutaneous tissue disorders	Cafe au lait spots	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Skin and subcutaneous tissue disorders	Cafe au lait spots	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Cafe au lait spots	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Keratosis pilaris		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Skin and subcutaneous tissue disorders	Keratosis pilaris	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Skin and subcutaneous tissue disorders	Keratosis pilaris	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Keratosis pilaris	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Skin and subcutaneous tissue disorders	Pityriasis alba		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635
Skin and subcutaneous tissue disorders	Pityriasis alba	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Skin and subcutaneous tissue disorders	Pityriasis alba	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Pityriasis alba	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Skin and subcutaneous tissue disorders	Rash erythematous		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635
Skin and subcutaneous tissue disorders	Rash erythematous	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Skin and subcutaneous tissue disorders	Rash erythematous	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Skin and subcutaneous tissue disorders	Rash erythematous	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Rash pruritic		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.644
Skin and subcutaneous tissue disorders	Rash pruritic	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Rash pruritic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.644

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Skin and subcutaneous tissue disorders	Rash pruritic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Dermatitis		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633
Skin and subcutaneous tissue disorders	Dermatitis	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Skin and subcutaneous tissue disorders	Dermatitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Dermatitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Dyshidrotic eczema		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Urticaria chronic		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.821

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Skin and subcutaneous tissue disorders	Urticaria chronic	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.821
Skin and subcutaneous tissue disorders	Urticaria chronic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Urticaria chronic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Petechiae		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Skin and subcutaneous tissue disorders	Petechiae	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Petechiae	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Skin and subcutaneous tissue disorders	Petechiae	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Musculoskeletal and connective tissue disorders			8.6% (5.1, 14.3)	7.1% (3.2, 15.0)	P=0.212, I <sup>2</sup> =33.9%	P=0.001, I <sup>2</sup> =0%							P=0.983
Musculoskeletal and connective tissue disorders		Mild	7.3% (4.1, 12.7)	7.1% (3.2, 15.0)	P=0.511, I <sup>2</sup> =0%	P=0.001, I <sup>2</sup> =0%	1.010 (0.357, 2.856)	1.009 (0.392, 2.599) 0.985	0.001 (-0.068 - 0.069)	P=0.089, I <sup>2</sup> =6552%	P=0.090, I <sup>2</sup> =6511%	P=0.039, I <sup>2</sup> =7665%	P=0.885
Musculoskeletal and connective tissue disorders		Moderate	1.3% (0.3, 5.1)	0%	P=0.073, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.503

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Musculoskeletal and connective tissue disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Musculoskeletal and connective tissue disorders	Pain in extremity		3.3% (1.4, 7.7)	4.8% (1.8, 12.0)	P=0.495, I <sup>2</sup> =0%	P=0.009, I <sup>2</sup> =0%							P=0.859
Musculoskeletal and connective tissue disorders	Pain in extremity	Mild	2.6% (1.0, 6.8)	4.8% (1.8, 12.0)	P=0.840, I <sup>2</sup> =0%	P=0.009, I <sup>2</sup> =0%	0.538 (0.132, 2.197)	0.551 (0.143, 2.126) 0.387	-0.022 (-0.074, -0.031)	P=0.167, I <sup>2</sup> =476 7%	P=0.174, I <sup>2</sup> =458 8%	P=0.044, I <sup>2</sup> =754 5%	P=0.977

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Musculoskel etal and connective tissue disorders	Pain in extremity	Moderate	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.635
Musculoskel etal and connective tissue disorders	Pain in extremity	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Musculoskel etal and connective tissue disorders	Arthralgia		4.0% (1.8, 8.6)	1.2% (0.2, 8.0)	P=0.276 , I <sup>2</sup> =9.8%	P=0.198 , I <sup>2</sup> =0%							P=0.513

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Musculoskeletal and connective tissue disorders	Arthralgia	Mild	4.0% (1.8, 8.6)	1.2% (0.2, 8.0)	P=0.276, I <sup>2</sup> =9.8%	P=0.198, I <sup>2</sup> =0%	3.436 (0.402, 29.368)	3.293 (0.409, 26.520) 0.263	0.028 (-0.011 - 0.066)	P=0.699, I <sup>2</sup> =0%	P=0.698, I <sup>2</sup> =0%	P=0.717, I <sup>2</sup> =0%	P=0.513
Musculoskeletal and connective tissue disorders	Arthralgia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Musculoskel etal and connective tissue disorders	Arthralgia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Musculoskel etal and connective tissue disorders	Musculoskel etal pain		1.3% (0.3, 5.1)	0%	P=0.073 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.503
Musculoskel etal and connective tissue disorders	Musculoskel etal pain	Mild	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Musculoskeletal and connective tissue disorders	Neck pain		0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.205, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%							P=0.905

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Musculoskeletal and connective tissue disorders	Neck pain	Mild	0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.205, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	0.537 (0.033, 8.847)	0.544 (0.035, 8.450) 0.664	-0.005 (-0.032, 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.905
Musculoskeletal and connective tissue disorders	Neck pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Musculoskeletal and connective tissue disorders	Neck pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Musculoskeletal and connective tissue disorders	Arthritis reactive		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635
Musculoskeletal and connective tissue disorders	Arthritis reactive	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Musculoskeletal and connective tissue disorders	Arthritis reactive	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Musculoskeletal and connective tissue disorders	Arthritis reactive	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Musculoskeletal and connective tissue disorders	Back pain		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Musculoskeletal and connective tissue disorders	Back pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Musculoskeletal and connective tissue disorders	Back pain	Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Musculoskeletal and connective tissue disorders	Back pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Musculoskeletal and connective tissue disorders	Neck mass		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635
Musculoskeletal and connective tissue disorders	Neck mass	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Musculoskeletal and connective tissue disorders	Neck mass	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Musculoskeletal and connective tissue disorders	Neck mass	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Musculoskeletal and connective tissue disorders	Pain in jaw		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635
Musculoskeletal and connective tissue disorders	Pain in jaw	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Musculoskeletal and connective tissue disorders	Pain in jaw	Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Musculoskeletal and connective tissue disorders	Pain in jaw	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Musculoskeletal and connective tissue disorders	Synovial cyst		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%							P=0.815

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Musculoskeletal and connective tissue disorders	Synovial cyst	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.815
Musculoskeletal and connective tissue disorders	Synovial cyst	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Musculoskel etal and connective tissue disorders	Synovial cyst	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Musculoskel etal and connective tissue disorders	Scoliosis		0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.633
Musculoskel etal and connective tissue disorders	Scoliosis	Mild	0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Musculoskeletal and connective tissue disorders	Scoliosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Musculoskeletal and connective tissue disorders	Scoliosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Metabolism and nutrition disorders			7.3% (4.1, 12.7)	9.5% (4.8, 17.9)	P=0.007, I <sup>2</sup> =77%	P=0.002, I <sup>2</sup> =0%							P=0.919



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Metabolism and nutrition disorders		Mild	7.3% (4.1, 12.7)	9.5% (4.8, 17.9)	P=0.007, I <sup>2</sup> =77%	P=0.002, I <sup>2</sup> =0%	0.746 (0.279, 1.992)	0.777 (0.334, 1.809) 0.558	-0.021 (-0.094, 0.052)	P=0.593, I <sup>2</sup> =0%	P=0.609, I <sup>2</sup> =0%	P=0.213, I <sup>2</sup> =3543%	P=0.919
Metabolism and nutrition disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Metabolism and nutrition disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Metabolism and nutrition disorders	Hypertriglyceridaemia		4.6% (2.2, 9.4)	2.4% (0.6, 9.0)	P=0.003, I <sup>2</sup> =0%	P=0.124, I <sup>2</sup> =0%							P=0.398

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Metabolism and nutrition disorders	Hypertriglyceridaemia	Mild	4.6% (2.2, 9.4)	2.4% (0.6, 9.0)	P=0.003, I <sup>2</sup> =0%	P=0.124, I <sup>2</sup> =0%	2.072 (0.413, 10.411)	1.982 (0.429, 9.155) 0.381	0.023 (-0.023 - 0.069)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.398
Metabolism and nutrition disorders	Hypertriglyceridaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Metabolism and nutrition disorders	Hypertriglyceridaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Metabolism and nutrition disorders	Hypercholesterolaemia		2.0% (0.6, 6.0)	3.6% (1.2, 10.5)	P=0.056, I <sup>2</sup> =0%	P=0.059, I <sup>2</sup> =0%							P=0.881
Metabolism and nutrition disorders	Hypercholesterolaemia	Mild	2.0% (0.6, 6.0)	3.6% (1.2, 10.5)	P=0.056, I <sup>2</sup> =0%	P=0.059, I <sup>2</sup> =0%	0.550 (0.106, 2.841)	0.566 (0.119, 2.694) 0.475	-0.015 (-0.060, 0.030)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.881
Metabolism and nutrition disorders	Hypercholesterolaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Metabolism and nutrition disorders	Hypercholesterolaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Metabolism and nutrition disorders	Decreased appetite		1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.120, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.670
Metabolism and nutrition disorders	Decreased appetite	Mild	1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.120, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	1.136 (0.100, 12.870)	1.133 (0.105, 12.159) 0.918	0.002 (-0.028, 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.670
Metabolism and nutrition disorders	Decreased appetite	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Metabolism and nutrition disorders	Decreased appetite	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Metabolism and nutrition disorders	Hyperuricaemia		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.539
Metabolism and nutrition disorders	Hyperuricaemia	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.539
Metabolism and nutrition disorders	Hyperuricaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Metabolism and nutrition disorders	Hyperuricaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Metabolism and nutrition disorders	Polydipsia		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635
Metabolism and nutrition disorders	Polydipsia	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Metabolism and nutrition disorders	Polydipsia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Metabolism and nutrition disorders	Polydipsia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Metabolism and nutrition disorders	Calcium deficiency		0%	1.2% (0.2, 8.0)	P=1.000 , I <sup>2</sup> =0%	P=0.279 , I <sup>2</sup> =0%							P=0.819
Metabolism and nutrition disorders	Calcium deficiency	Mild	0%	1.2% (0.2, 8.0)	P=1.000 , I <sup>2</sup> =0%	P=0.279 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.819

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Metabolism and nutrition disorders	Calcium deficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Metabolism and nutrition disorders	Calcium deficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Metabolism and nutrition disorders	Hyperglycaemia		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.819



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Metabolism and nutrition disorders	Hyperglycaemia	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.819
Metabolism and nutrition disorders	Hyperglycaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Metabolism and nutrition disorders	Hyperglycaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Metabolism and nutrition disorders	Hyperlipidaemia		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.819

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Metabolism and nutrition disorders	Hyperlipidaemia	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.819
Metabolism and nutrition disorders	Hyperlipidaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Metabolism and nutrition disorders	Hyperlipidaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Eye disorders			7.3% (4.1, 12.7)	1.2% (0.2, 8.0)	P=0.545, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.017

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Eye disorders		Mild	6.6% (3.6, 11.9)	1.2% (0.2, 8.0)	P=0.740, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	5.964 (0.743, 47.857)	5.605 (0.727, 43.235) 0.098	0.054 (0.009 - 0.100)	P=0.636, I <sup>2</sup> =0%	P=0.633, I <sup>2</sup> =0%	P=0.904, I <sup>2</sup> =0%	P=0.022
Eye disorders		Moderate	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Eye disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Eye disorders	Refraction disorder		1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.120, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.570

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Eye disorders	Refraction disorder	Mild	1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.120 , I <sup>2</sup> =0%	P=0.279 , I <sup>2</sup> =0%	1.136 (0.100, 12.870)	1.133 (0.105, 12.159) 0.918	0.002 (-0.028 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.570
Eye disorders	Refraction disorder	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Eye disorders	Refraction disorder	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Eye disorders	Conjunctivitis allergic		1.3% (0.3, 5.1)	0%	P=0.887 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.460

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Eye disorders	Conjunctivitis allergic	Mild	1.3% (0.3, 5.1)	0%	P=0.887, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.031)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.738, I <sup>2</sup> =0%	P=0.460
Eye disorders	Conjunctivitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Eye disorders	Conjunctivitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Eye disorders	Eye swelling		1.3% (0.3, 5.1)	0%	P=0.887, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.460

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Eye disorders	Eye swelling	Mild	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.635
Eye disorders	Eye swelling	Moderate	0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.633
Eye disorders	Eye swelling	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Eye disorders	Strabismus		0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.387

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Eye disorders	Strabismus	Mild	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.387
Eye disorders	Strabismus	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Eye disorders	Strabismus	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Eye disorders	Myopia		0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.385

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Eye disorders	Myopia	Mild	0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.385
Eye disorders	Myopia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Eye disorders	Myopia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Eye disorders	Eye haemorrhage		0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.635
Eye disorders	Eye haemorrhage	Mild	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.635



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Eye disorders	Eye haemorrhage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Eye disorders	Eye haemorrhage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Eye disorders	Astigmatism		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808
Eye disorders	Astigmatism	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Eye disorders	Astigmatism	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Eye disorders	Astigmatism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Eye disorders	Corneal epithelium defect		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633
Eye disorders	Corneal epithelium defect	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Eye disorders	Corneal epithelium defect	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Eye disorders	Corneal epithelium defect	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Eye disorders	Eye pain		0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.633
Eye disorders	Eye pain	Mild	0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Eye disorders	Eye pain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Eye disorders	Eye pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Eye disorders	Xerophthal mia		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.819
Eye disorders	Xerophthal mia	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.819
Eye disorders	Xerophthal mia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Eye disorders	Xerophthal mia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Eye disorders	Vernal keratoconjun ctivitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.620
Eye disorders	Vernal keratoconjun ctivitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.620
Eye disorders	Vernal keratoconjun ctivitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Eye disorders	Vernal keratoconjun ctivitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Eye disorders	Vitreous opacities		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.821
Eye disorders	Vitreous opacities	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.821
Eye disorders	Vitreous opacities	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Eye disorders	Vitreous opacities	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Eye disorders	Hypermetropia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Eye disorders	Hypermetropia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Eye disorders	Hypermetropia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Eye disorders	Hypermetropia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Eye disorders	Papilloedema		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Eye disorders	Papilloedema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Eye disorders	Papilloedema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Eye disorders	Papilloedema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Blood and lymphatic system disorders			5.3% (2.7, 10.2)	2.4% (0.6, 9.0)	P=0.658, I <sup>2</sup> =0%	P=0.864, I <sup>2</sup> =0%							P=0.700



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Blood and lymphatic system disorders		Mild	4.0% (1.8, 8.6)	2.4% (0.6, 9.0)	P=0.552 , I <sup>2</sup> =0%	P=0.864 , I <sup>2</sup> =0%	1.700 (0.336, 8.596)	1.672 (0.346, 8.089) 0.522	0.016 (-0.029 - 0.061)	P=0.65 1, I <sup>2</sup> =0%	P=0.65 3, I <sup>2</sup> =0%	P=0.59 4, I <sup>2</sup> =0%	P=0.860
Blood and lymphatic system disorders		Moderate	1.3% (0.3, 5.1)	0%	P=0.887 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.031)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.73 8, I <sup>2</sup> =0%	P=0.460
Blood and lymphatic system disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Blood and lymphatic system disorders	Lymphaden opathy		0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.205 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%							P=0.905

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Blood and lymphatic system disorders	Lymphaden opathy	Mild	0%	1.2% (0.2, 8.0)	P=1.000 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.815
Blood and lymphatic system disorders	Lymphaden opathy	Moderate	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.635
Blood and lymphatic system disorders	Lymphaden opathy	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Blood and lymphatic system disorders	Anaemia		0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.205, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.898
Blood and lymphatic system disorders	Anaemia	Mild	0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.205, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	0.552 (0.034, 8.955)	0.552 (0.034, 9.073) 0.677	-0.005 (-0.032, 0.021)	P=0.345, I <sup>2</sup> =0%	P=0.346, I <sup>2</sup> =0%	P=0.352, I <sup>2</sup> =0%	P=0.898
Blood and lymphatic system disorders	Anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Blood and lymphatic system disorders	Anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Blood and lymphatic system disorders	Neutropenia		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Blood and lymphatic system disorders	Neutropenia	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
Blood and lymphatic system disorders	Neutropenia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Blood and lymphatic system disorders	Neutropenia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Blood and lymphatic system disorders	Granulocyto penia		1.3% (0.3, 5.1)	0%	P=0.120 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.500
Blood and lymphatic system disorders	Granulocyto penia	Mild	1.3% (0.3, 5.1)	0%	P=0.120 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.500
Blood and lymphatic system disorders	Granulocyto penia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Blood and lymphatic system disorders	Granulocyto penia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Blood and lymphatic system disorders	Lymphadeni tis		1.3% (0.3, 5.1)	0%	P=0.120 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.500
Blood and lymphatic system disorders	Lymphadeni tis	Mild	1.3% (0.3, 5.1)	0%	P=0.120 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.032)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.500

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Blood and lymphatic system disorders	Lymphadenitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Blood and lymphatic system disorders	Lymphadenitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Blood and lymphatic system disorders	Iron deficiency anaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808
Blood and lymphatic system disorders	Iron deficiency anaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Blood and lymphatic system disorders	Iron deficiency anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Blood and lymphatic system disorders	Iron deficiency anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Blood and lymphatic system disorders	Thymus disorder		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Blood and lymphatic system disorders	Thymus disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Blood and lymphatic system disorders	Thymus disorder	Moderate	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Blood and lymphatic system disorders	Thymus disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Blood and lymphatic system disorders	Hypochromic anaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Blood and lymphatic system disorders	Hypochromic anaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Blood and lymphatic system disorders	Hypochromic anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Blood and lymphatic system disorders	Hypochromic anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Immune system disorders			4.6% (2.2, 9.4)	3.6% (1.2, 10.5)	P=0.022, I <sup>2</sup> =72.1%	P=0.422, I <sup>2</sup> =0%							P=0.799

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Immune system disorders		Mild	4.0% (1.8, 8.6)	3.6% (1.2, 10.5)	P=0.048 , I <sup>2</sup> =65%	P=0.422 , I <sup>2</sup> =0%	1.104 (0.266, 4.578)	1.098 (0.284, 4.248) 0.892	0.004 (-0.047 - 0.054)	P=0.586, I <sup>2</sup> =0%	P=0.589, I <sup>2</sup> =0%	P=0.536, I <sup>2</sup> =0%	P=0.881
Immune system disorders		Moderate	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Immune system disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Immune system disorders	Seasonal allergy		2.0% (0.6, 6.0)	1.2% (0.2, 8.0)	P=0.027 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%							P=0.821

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Immune system disorders	Seasonal allergy	Mild	2.0% (0.6, 6.0)	1.2% (0.2, 8.0)	P=0.027, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	1.662 (0.167, 16.564)	1.632 (0.176, 15.142) 0.666	0.008 (-0.024 - 0.039)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.821
Immune system disorders	Seasonal allergy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Immune system disorders	Seasonal allergy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Immune system disorders	Hypersensitivity		0.7% (0.1, 4.5)	2.4% (0.6, 9.0)	P=0.205, I <sup>2</sup> =0%	P=0.864, I <sup>2</sup> =0%							P=0.886

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Immune system disorders	Hypersensitivity	Mild	0%	2.4% (0.6, 9.0)	P=1.000, I <sup>2</sup> =0%	P=0.864, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.024 (-0.056 - 0.009)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.796, I <sup>2</sup> =0%	P=0.627
Immune system disorders	Hypersensitivity	Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Immune system disorders	Hypersensitivity	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Immune system disorders	Allergy to animal		1.3% (0.3, 5.1)	0%	P=0.073, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.503

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Immune system disorders	Allergy to animal	Mild	1.3% (0.3, 5.1)	0%	P=0.073 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.503
Immune system disorders	Allergy to animal	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Immune system disorders	Allergy to animal	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Immune system disorders	Food allergy		0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.633

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Immune system disorders	Food allergy	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Immune system disorders	Food allergy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Immune system disorders	Food allergy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Endocrine disorders			2.0% (0.6, 6.0)	3.6% (1.2, 10.5)	P=0.446, I <sup>2</sup> =0%	P=0.024, I <sup>2</sup> =0%							P=0.870

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Endocrine disorders		Mild	1.3% (0.3, 5.1)	3.6% (1.2, 10.5)	P=0.887, I <sup>2</sup> =0%	P=0.024, I <sup>2</sup> =0%	0.358 (0.059, 2.166)	0.367 (0.063, 2.130) 0.264	-0.023 (-0.067, -0.021)	P=0.250, I <sup>2</sup> =245 5%	P=0.257, I <sup>2</sup> =222 7%	P=0.083, I <sup>2</sup> =667 6%	P=0.976
Endocrine disorders		Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006, 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.908
Endocrine disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Endocrine disorders	Secondary hypothyroidism		1.3% (0.3, 5.1)	3.6% (1.2, 10.5)	P=0.073, I <sup>2</sup> =0%	P=0.024, I <sup>2</sup> =0%							P=0.934



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Endocrine disorders	Secondary hypothyroidism	Mild	0.7% (0.1, 4.5)	3.6% (1.2, 10.5)	P=0.205, I <sup>2</sup> =0%	P=0.024, I <sup>2</sup> =0%	0.169 (0.017, 1.688)	0.181 (0.020, 1.682) 0.133	-0.029 (-0.071 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.715
Endocrine disorders	Secondary hypothyroidism	Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Endocrine disorders	Secondary hypothyroidism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Endocrine disorders	Hypothyroidism		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.890

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Endocrine disorders	Hypothyroid ism	Mild	0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.890
Endocrine disorders	Hypothyroid ism	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Endocrine disorders	Hypothyroid ism	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Endocrine disorders	Adrenal insufficiency		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.808
Endocrine disorders	Adrenal insufficiency	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Endocrine disorders	Adrenal insufficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808
Endocrine disorders	Adrenal insufficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Endocrine disorders	Precocious puberty		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.620
Endocrine disorders	Precocious puberty	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.620
Endocrine disorders	Precocious puberty	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Endocrine disorders	Precocious puberty	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Endocrine disorders	Diabetes insipidus		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Endocrine disorders	Diabetes insipidus	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Endocrine disorders	Diabetes insipidus	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Endocrine disorders	Diabetes insipidus	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Endocrine disorders	Secondary adrenocortical insufficiency		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Endocrine disorders	Secondary adrenocortical insufficiency	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Endocrine disorders	Secondary adrenocortical insufficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Endocrine disorders	Secondary adrenocortical insufficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Reproductive system and breast disorders			2.0% (0.6, 6.0)	2.4% (0.6, 9.0)	P=0.056, I <sup>2</sup> =0%	P=0.068, I <sup>2</sup> =0%							P=0.724
Reproductive system and breast disorders		Mild	2.0% (0.6, 6.0)	2.4% (0.6, 9.0)	P=0.056, I <sup>2</sup> =0%	P=0.068, I <sup>2</sup> =0%	0.837 (0.141, 4.971)	0.837 (0.142, 4.928)	-0.004 (-0.044, 0.036)	P=0.089, I <sup>2</sup> =6534%	P=0.093, I <sup>2</sup> =6466%	P=0.060, I <sup>2</sup> =7163%	P=0.724
Reproductive system and breast disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Reproductiv e system and breast disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Reproductiv e system and breast disorders	Penile adhesion		0%	2.4% (0.6, 9.0)	P=1.000 , I <sup>2</sup> =0%	P=0.068 , I <sup>2</sup> =0%							P=0.669
Reproductiv e system and breast disorders	Penile adhesion	Mild	0%	2.4% (0.6, 9.0)	P=1.000 , I <sup>2</sup> =0%	P=0.068 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.024 (-0.057 - 0.009)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.669
Reproductiv e system and breast disorders	Penile adhesion	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Reproductiv e system and breast disorders	Penile adhesion	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Reproductiv e system and breast disorders	Gynaecomas tia		0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.890
Reproductiv e system and breast disorders	Gynaecomas tia	Mild	0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.890



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Reproductive system and breast disorders	Gynaecomastia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Reproductive system and breast disorders	Gynaecomastia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Reproductive system and breast disorders	Genital discomfort		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%							P=0.815
Reproductive system and breast disorders	Genital discomfort	Mild	0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.815

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Reproductiv e system and breast disorders	Genital discomfort	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Reproductiv e system and breast disorders	Genital discomfort	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Reproductiv e system and breast disorders	Pelvic fluid collection		0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.633

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Reproductiv e system and breast disorders	Pelvic fluid collection	Mild	0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.633
Reproductiv e system and breast disorders	Pelvic fluid collection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Reproductiv e system and breast disorders	Pelvic fluid collection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Reproductiv e system and breast disorders	Testicular appendage torsion		0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.633

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Reproductiv e system and breast disorders	Testicular appendage torsion	Mild	0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.633
Reproductiv e system and breast disorders	Testicular appendage torsion	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Reproductiv e system and breast disorders	Testicular appendage torsion	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Reproductive system and breast disorders	Balanoposthitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.821
Reproductive system and breast disorders	Balanoposthitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.821
Reproductive system and breast disorders	Balanoposthitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Reproductive system and breast disorders	Balanoposthitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Ear and labyrinth disorders			2.6% (1.0, 6.8)	1.2% (0.2, 8.0)	P=0.217, I <sup>2</sup> =23.2%	P=0.279, I <sup>2</sup> =0%							P=0.778
Ear and labyrinth disorders		Mild	2.6% (1.0, 6.8)	1.2% (0.2, 8.0)	P=0.217, I <sup>2</sup> =23.2%	P=0.279, I <sup>2</sup> =0%	2.237 (0.247, 20.226)	2.222 (0.247, 20.003) 0.476	0.014 (-0.020 - 0.049)	P=0.297, I <sup>2</sup> =798%	P=0.297, I <sup>2</sup> =788%	P=0.225, I <sup>2</sup> =319%	P=0.778
Ear and labyrinth disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Ear and labyrinth disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Ear and labyrinth disorders	Ear pain		2.0% (0.6, 6.0)	0%	P=0.027, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.648
Ear and labyrinth disorders	Ear pain	Mild	2.0% (0.6, 6.0)	0%	P=0.027, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.020 (-0.003 - 0.042)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.648
Ear and labyrinth disorders	Ear pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Ear and labyrinth disorders	Ear pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Ear and labyrinth disorders	Cerumen impaction		0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%							P=0.819

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Ear and labyrinth disorders	Cerumen impaction	Mild	0%	1.2% (0.2, 8.0)	P=1.000 , I <sup>2</sup> =0%	P=0.279 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.819
Ear and labyrinth disorders	Cerumen impaction	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Ear and labyrinth disorders	Cerumen impaction	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Ear and labyrinth disorders	Motion sickness		0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.633



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Ear and labyrinth disorders	Motion sickness	Mild	0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.633
Ear and labyrinth disorders	Motion sickness	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Ear and labyrinth disorders	Motion sickness	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Psychiatric disorders			2.0% (0.6, 6.0)	1.2% (0.2, 8.0)	P=0.027 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%							P=0.821

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Psychiatric disorders		Mild	2.0% (0.6, 6.0)	1.2% (0.2, 8.0)	P=0.027, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	1.662 (0.167, 16.564)	1.632 (0.176, 15.142) 0.666	0.008 (-0.024 - 0.039)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.541
Psychiatric disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808
Psychiatric disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Psychiatric disorders	Attention deficit/hyperactivity disorder		0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.205, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%							P=0.905

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Psychiatric disorders	Attention deficit/hyper activity disorder	Mild	0.7% (0.1, 4.5)	1.2% (0.2, 8.0)	P=0.205, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	0.537 (0.033, 8.847)	0.544 (0.035, 8.450) 0.664	-0.005 (-0.032, 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.905
Psychiatric disorders	Attention deficit/hyper activity disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Psychiatric disorders	Attention deficit/hyper activity disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Psychiatric disorders	Affect lability		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635
Psychiatric disorders	Affect lability	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006, 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Psychiatric disorders	Affect lability	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Psychiatric disorders	Affect lability	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Psychiatric disorders	Enuresis		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635
Psychiatric disorders	Enuresis	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Psychiatric disorders	Enuresis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Psychiatric disorders	Enuresis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Psychiatric disorders	Depressive symptom		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808
Psychiatric disorders	Depressive symptom	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Psychiatric disorders	Depressive symptom	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.808

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Psychiatric disorders	Depressive symptom	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			2.0% (0.6, 6.0)	1.2% (0.2, 8.0)	P=0.027 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%							P=0.541

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Mild	2.0% (0.6, 6.0)	1.2% (0.2, 8.0)	P=0.027, I <sup>2</sup> =0%	P=0.198, I <sup>2</sup> =0%	1.662 (0.167, 16.564)	1.632 (0.176, 15.142) 0.666	0.008 (-0.024 - 0.039)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.541
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma		1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.073 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%							P=0.677
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Mild	1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.073 , I <sup>2</sup> =0%	P=0.198 , I <sup>2</sup> =0%	1.091 (0.096, 12.448)	1.088 (0.102, 11.604) 0.944	0.001 (-0.028 - 0.030)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.677

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma		0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.635
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Mild	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Cardiac disorders			2.6% (1.0, 6.8)	0%	P=0.840 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.296
Cardiac disorders		Mild	2.0% (0.6, 6.0)	0%	P=0.677 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.020 (-0.002 - 0.042)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.656, I <sup>2</sup> =0%	P=0.368
Cardiac disorders		Moderate	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Cardiac disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Cardiac disorders	Sinoatrial block		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635
Cardiac disorders	Sinoatrial block	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Cardiac disorders	Sinoatrial block	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Cardiac disorders	Sinoatrial block	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Cardiac disorders	Sinus tachycardia		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635
Cardiac disorders	Sinus tachycardia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Cardiac disorders	Sinus tachycardia	Moderate	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Cardiac disorders	Sinus tachycardia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Cardiac disorders	Tachycardia		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635
Cardiac disorders	Tachycardia	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Cardiac disorders	Tachycardia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Cardiac disorders	Tachycardia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Cardiac disorders	Myocarditis		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633
Cardiac disorders	Myocarditis	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Cardiac disorders	Myocarditis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Cardiac disorders	Myocarditis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Cardiac disorders	Wandering pacemaker		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Cardiac disorders	Wandering pacemaker	Mild	0.7% (0.1, 4.5)	0%	P=0.273 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Cardiac disorders	Wandering pacemaker	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Cardiac disorders	Wandering pacemaker	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Renal and urinary disorders			1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.073 , I <sup>2</sup> =0%	P=0.279 , I <sup>2</sup> =0%							P=0.754

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Renal and urinary disorders		Mild	1.3% (0.3, 5.1)	1.2% (0.2, 8.0)	P=0.073, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	1.104 (0.099, 12.299)	1.104 (0.098, 12.441) 0.936	0.001 (-0.028 - 0.031)	P=0.215, I <sup>2</sup> =349 5%	P=0.217, I <sup>2</sup> =344 8%	P=0.211, I <sup>2</sup> =361 6%	P=0.754
Renal and urinary disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Renal and urinary disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Renal and urinary disorders	Pollakiuria		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Renal and urinary disorders	Pollakiuria	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Renal and urinary disorders	Pollakiuria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Renal and urinary disorders	Pollakiuria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Renal and urinary disorders	Polyuria		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Renal and urinary disorders	Polyuria	Mild	0.7% (0.1, 4.5)	0%	P=0.205 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.635
Renal and urinary disorders	Polyuria	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Renal and urinary disorders	Polyuria	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Renal and urinary disorders	Nocturia		0%	1.2% (0.2, 8.0)	P=1.000 , I <sup>2</sup> =0%	P=0.279 , I <sup>2</sup> =0%							P=0.819
Renal and urinary disorders	Nocturia	Mild	0%	1.2% (0.2, 8.0)	P=1.000 , I <sup>2</sup> =0%	P=0.279 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.012 (-0.035 - 0.011)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=0.819

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Renal and urinary disorders	Nocturia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Renal and urinary disorders	Nocturia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.908
Vascular disorders			1.3% (0.3, 5.1)	0%	P=0.887 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							P=0.460
Vascular disorders		Mild	1.3% (0.3, 5.1)	0%	P=0.887 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.013 (-0.005 - 0.031)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.738, I <sup>2</sup> =0%	P=0.460

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Vascular disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Vascular disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Vascular disorders	Hypotension		0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.635
Vascular disorders	Hypotension	Mild	0.7% (0.1, 4.5)	0%	P=0.205, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.019)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Vascular disorders	Hypotension	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Vascular disorders	Hypotension	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Vascular disorders	Cyanosis		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633
Vascular disorders	Cyanosis	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633
Vascular disorders	Cyanosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Vascular disorders	Cyanosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Congenital, familial and genetic disorders			0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.890
Congenital, familial and genetic disorders		Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.890

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Congenital, familial and genetic disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Congenital, familial and genetic disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Congenital, familial and genetic disorders	Supernumerary teeth		0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.633
Congenital, familial and genetic disorders	Supernumerary teeth	Mild	0.7% (0.1, 4.5)	0%	P=0.273, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.633

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated idiopathic													
Congenital, familial and genetic disorders	Supernumerary teeth	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Congenital, familial and genetic disorders	Supernumerary teeth	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Congenital, familial and genetic disorders	Buried penis syndrome		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.821

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Congenital, familial and genetic disorders	Buried penis syndrome	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.821
Congenital, familial and genetic disorders	Buried penis syndrome	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Congenital, familial and genetic disorders	Buried penis syndrome	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Hepatobiliary disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.644

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Hepatobiliary disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.644
Hepatobiliary disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Hepatobiliary disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Hepatobiliary disorders	Hepatomegaly		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.644
Hepatobiliary disorders	Hepatomegaly	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.644

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic													
Hepatobiliary disorders	Hepatomegaly	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Hepatobiliary disorders	Hepatomegaly	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Any adverse event			87.9% (71.8, 95.4)	64.3% (37.6, 84.3)	P=0.028 , I <sup>2</sup> =0%	P=0.015 , I <sup>2</sup> =0%							
Any adverse event		Mild	72.7% (55.3, 85.2)	57.1% (31.6, 79.4)	P=0.018 , I <sup>2</sup> =74.4 %	P=0.006 , I <sup>2</sup> =0%	2.104 (0.459, 9.651)	1.216 (0.789, 1.876) 0.376	0.126 (-0.139 - 0.391)	P=0.524, I <sup>2</sup> =0%	P=0.112, I <sup>2</sup> =603 1%	P=0.225, I <sup>2</sup> =320 1%	
Any adverse event		Moderate	12.1% (4.6, 28.2)	7.1% (1.0, 37.0)	P=0.028 , I <sup>2</sup> =0%	P=0.336 , I <sup>2</sup> =0%	2.133 (0.203, 22.444)	1.895 (0.246, 14.612) 0.54	0.062 (-0.108 - 0.232)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Any adverse event		Severe	3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations			60.6% (43.4, 75.6)	42.9% (20.6, 68.4)	P=0.271, I <sup>2</sup> =14.7%	P=0.032, I <sup>2</sup> =73%							
Infections and infestations		Mild	54.5% (37.7, 70.4)	42.9% (20.6, 68.4)	P=0.333, I <sup>2</sup> =0%	P=0.032, I <sup>2</sup> =73%	1.541 (0.410, 5.789)	1.222 (0.647, 2.308) 0.536	0.098 (-0.199 - 0.395)	P=0.210, I <sup>2</sup> =3627%	P=0.103, I <sup>2</sup> =6230%	P=0.150, I <sup>2</sup> =5177%	
Infections and infestations		Moderate	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations		Severe	3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Upper respiratory tract infection		24.2% (12.6, 41.5)	28.6% (11.1, 56.1)	P=0.002, I <sup>2</sup> =83.9%	P=0.053, I <sup>2</sup> =68%							
Infections and infestations	Upper respiratory tract infection	Mild	24.2% (12.6, 41.5)	28.6% (11.1, 56.1)	P=0.002, I <sup>2</sup> =83.9%	P=0.053, I <sup>2</sup> =68%	0.585 (0.108, 3.173)	0.749 (0.313, 1.789) 0.515	-0.074 (-0.313 - 0.164)	P=0.823, I <sup>2</sup> =0%	P=0.680, I <sup>2</sup> =0%	P=0.867, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Upper respiratory tract infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Upper respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Nasopharyngitis		18.2% (8.4, 35.0)	14.3% (3.6, 42.7)	P=0.139, I <sup>2</sup> =42.8%	P=0.029, I <sup>2</sup> =0%							
Infections and infestations	Nasopharyngitis	Mild	18.2% (8.4, 35.0)	14.3% (3.6, 42.7)	P=0.139, I <sup>2</sup> =42.8%	P=0.029, I <sup>2</sup> =0%	1.290 (0.258, 6.451)	1.269 (0.290, 5.563) 0.752	0.041 (-0.205, 0.286)	P=0.038, I <sup>2</sup> =7678%	P=0.041, I <sup>2</sup> =7613%	P=0.027, I <sup>2</sup> =7957%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Nasopharyngitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Nasopharyngitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis		12.1% (4.6, 28.2)	0%	P=0.440, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis	Mild	9.1% (3.0, 24.7)	0%	P=0.735, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.093 (-0.007 - 0.192)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.561, I <sup>2</sup> =0%	
Infections and infestations	Pharyngitis	Moderate	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Infections and infestations	Pharyngitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Bronchitis		3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Bronchitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Bronchitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Infections and infestations	Bronchitis	Severe	3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Respiratory tract infection		3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection	Mild	3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Respiratory tract infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis		3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis	Mild	3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Tonsillitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Rhinitis		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rhinitis	Mild	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Rhinitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rhinitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Infections and infestations	Pharyngitis streptococcal		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis streptococcal	Mild	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pharyngitis streptococcal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis streptococcal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Infections and infestations	Sinusitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinusitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinusitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinusitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis		3.0% (0.4, 18.6)	7.1% (1.0, 37.0)	P=0.185, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Infections and infestations	Gastroenteritis	Mild	3.0% (0.4, 18.6)	7.1% (1.0, 37.0)	P=0.185, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%	0.308 (0.015, 6.117)	0.357 (0.027, 4.699) 0.434	-0.048 (-0.193, 0.096)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Gastroenteritis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Ear infection		0%	7.1% (1.0, 37.0)	P=1.000, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Ear infection	Mild	0%	7.1% (1.0, 37.0)	P=1.000 , I <sup>2</sup> =0%	P=0.336 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.069 (-0.203 - 0.064)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Infections and infestations	Ear infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Ear infection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pneumonia		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pneumonia	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Pneumonia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pneumonia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis		0%	7.1% (1.0, 37.0)	P=1.000 , I <sup>2</sup> =0%	P=0.138 , I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis	Mild	0%	7.1% (1.0, 37.0)	P=1.000 , I <sup>2</sup> =0%	P=0.138 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.075 (-0.213 - 0.063)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Conjunctivitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis viral		3.0% (0.4, 18.6)	7.1% (1.0, 37.0)	P=0.288, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis viral	Mild	3.0% (0.4, 18.6)	7.1% (1.0, 37.0)	P=0.288, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%	0.436 (0.030, 6.295)	0.436 (0.033, 5.786) 0.529	-0.042 (-0.197, 0.112)	P=0.261, I <sup>2</sup> =208 5%	P=0.277, I <sup>2</sup> =155 0%	P=0.227, I <sup>2</sup> =316 1%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Infections and infestations	Gastroenteritis viral	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis viral	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis media acute		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis media acute	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis media acute	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Otitis media acute	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Viral infection		6.1% (1.5, 21.2)	0%	P=0.129 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Viral infection	Mild	6.1% (1.5, 21.2)	0%	P=0.129 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.066 (-0.019 - 0.150)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Infections and infestations	Viral infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Viral infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Varicella		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Varicella	Mild	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Varicella	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Varicella	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Respiratory tract infection viral		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection viral	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection viral	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Respiratory tract infection viral	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Enteritis infectious		3.0% (0.4, 18.6)	0%	P=0.288 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Enteritis infectious	Mild	3.0% (0.4, 18.6)	0%	P=0.288 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Enteritis infectious	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Infections and infestations	Enteritis infectious	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Influenza		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Influenza	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Influenza	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Influenza	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Otitis media		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis media	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis media	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis media	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Periodontitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Periodontitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Periodontitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Periodontitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Herpangina		3.0% (0.4, 18.6)	0%	P=0.185 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Infections and infestations	Herpangina	Mild	3.0% (0.4, 18.6)	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Herpangina	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Herpangina	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Helminthic infection		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Helminthic infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Helminthic infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Helminthic infection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pharyngoton sillitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pharyngoton sillitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Pharyngoton sillitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pharyngoton sillitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Hordeolum		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Hordeolum	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Hordeolum	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Hordeolum	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pulpitis dental		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pulpitis dental	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pulpitis dental	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pulpitis dental	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Infections and infestations	Urinary tract infection		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Urinary tract infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Urinary tract infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Urinary tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Viral upper respiratory tract infection		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral upper respiratory tract infection	Mild	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Viral upper respiratory tract infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral upper respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Laryngitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Laryngitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Laryngitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Laryngitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Oral herpes		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Oral herpes	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Oral herpes	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Oral herpes	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Hand-foot-and-mouth disease		3.0% (0.4, 18.6)	0%	P=0.185 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Infections and infestations	Hand-foot-and-mouth disease	Mild	3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Hand-foot-and-mouth disease	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hand-foot-and-mouth disease	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Appendicitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Appendicitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Appendicitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Appendicitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Atypical pneumonia		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Atypical pneumonia	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Atypical pneumonia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Atypical pneumonia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis bacterial		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis bacterial	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis bacterial	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Infections and infestations	Conjunctivitis bacterial	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Cystitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Cystitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Cystitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Cystitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Enterobiasis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Enterobiasis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Enterobiasis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Enterobiasis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Infected bite		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Infected bite	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Infected bite	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Infected bite	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Molluscum contagiosum		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Molluscum contagiosum	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Molluscum contagiosum	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Molluscum contagiosum	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis externa		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Otitis externa	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis externa	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis externa	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tinea pedis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tinea pedis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Tinea pedis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tinea pedis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tooth abscess		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tooth abscess	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tooth abscess	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Tooth abscess	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Vulvitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Vulvitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Vulvitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Infections and infestations	Vulvitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Croup infectious		0%	8.7% (2.2, 28.9)	P=1.000, I <sup>2</sup> =0%	P=0.597, I <sup>2</sup> =0%							
Infections and infestations	Croup infectious	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Croup infectious	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Croup infectious	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Eczema infected		3.0% (0.4, 18.6)	0%	P=0.288 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Eczema infected	Mild	3.0% (0.4, 18.6)	0%	P=0.288 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Eczema infected	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Eczema infected	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Abscess limb		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Abscess limb	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Abscess limb	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Abscess limb	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Bacterial infection		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Infections and infestations	Bacterial infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Bacterial infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Bacterial infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Chronic sinusitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Chronic sinusitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Chronic sinusitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Chronic sinusitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Chronic tonsillitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Chronic tonsillitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Chronic tonsillitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Chronic tonsillitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Folliculitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Folliculitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Folliculitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Infections and infestations	Folliculitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastrointestinal bacterial infection		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastrointestinal bacterial infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastrointestinal bacterial infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastrointestinal bacterial infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Herpes virus infection		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Herpes virus infection	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Herpes virus infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Herpes virus infection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Infectious mononucleosis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Infectious mononucleosis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Infectious mononucleosis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Infectious mononucleosis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Mumps		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Infections and infestations	Mumps	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Mumps	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Mumps	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Myringitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Myringitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Infections and infestations	Myringitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Myringitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Peritonsillar abscess		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Peritonsillar abscess	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Peritonsillar abscess	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Infections and infestations	Peritonsillar abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinobronchitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinobronchitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinobronchitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Infections and infestations	Sinobronchitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Subcutaneous abscess		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Subcutaneous abscess	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Subcutaneous abscess	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Subcutaneous abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Tonsillitis bacterial		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis bacterial	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis bacterial	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis bacterial	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tracheitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Tracheitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tracheitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tracheitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Laryngitis viral		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Laryngitis viral	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Laryngitis viral	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Laryngitis viral	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Rotavirus infection		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Rotavirus infection	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Infections and infestations	Rotavirus infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rotavirus infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations			30.3% (17.1, 47.7)	28.6% (11.1, 56.1)	P=0.000, I <sup>2</sup> =88.7%	P=0.053, I <sup>2</sup> =68%							
Investigations		Mild	30.3% (17.1, 47.7)	28.6% (11.1, 56.1)	P=0.000, I <sup>2</sup> =88.7%	P=0.053, I <sup>2</sup> =68%	0.861 (0.157, 4.719)	0.931 (0.417, 2.079) 0.862	-0.020 (-0.252, 0.212)	P=0.586, I <sup>2</sup> =0%	P=0.547, I <sup>2</sup> =0%	P=0.681, I <sup>2</sup> =0%	



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Insulin-like growth factor increased		12.1% (4.6, 28.2)	0%	P=0.006, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Insulin-like growth factor increased	Mild	12.1% (4.6, 28.2)	0%	P=0.006, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.108 (0.001 - 0.214)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Insulin-like growth factor increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Insulin-like growth factor increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood glucose increased		6.1% (1.5, 21.2)	21.4% (7.1, 49.4)	P=0.058, I <sup>2</sup> =0%	P=0.005, I <sup>2</sup> =0%							
Investigations	Blood glucose increased	Mild	6.1% (1.5, 21.2)	21.4% (7.1, 49.4)	P=0.058, I <sup>2</sup> =0%	P=0.005, I <sup>2</sup> =0%	0.111 (0.011, 1.145)	0.238 (0.055, 1.035) 0.056	-0.172 (-0.385, -0.041)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Investigation s	Blood glucose increased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood glucose increased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Low density lipoprotein increased		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Low density lipoprotein increased	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Low density lipoprotein increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Low density lipoprotein increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood alkaline phosphatase increased		3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Blood alkaline phosphatase increased	Mild	3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood alkaline phosphatase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood alkaline phosphatase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Eosinophil count increased		3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Eosinophil count increased	Mild	3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Eosinophil count increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Eosinophil count increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Blood iron increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood phosphorus increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood phosphorus increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Investigation s	Blood phosphorus increased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood phosphorus increased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood uric acid increased		3.0% (0.4, 18.6)	0%	P=0.185 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood uric acid increased	Mild	3.0% (0.4, 18.6)	0%	P=0.185 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Investigation s	Blood uric acid increased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Blood uric acid increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Alanine aminotransferase increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Alanine aminotransferase increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Alanine aminotransferase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Alanine aminotransferase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Blood triglycerides increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood triglycerides increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood triglycerides increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood triglycerides increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood glucose abnormal		3.0% (0.4, 18.6)	14.3% (3.6, 42.7)	P=0.185, I <sup>2</sup> =0%	P=0.029, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Blood glucose abnormal	Mild	3.0% (0.4, 18.6)	14.3% (3.6, 42.7)	P=0.185, I <sup>2</sup> =0%	P=0.029, I <sup>2</sup> =0%	0.115 (0.008, 1.732)	0.179 (0.020, 1.568) 0.12	-0.124 (-0.311 - 0.064)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood glucose abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood glucose abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Blood thyroid stimulating hormone increased		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigations	Blood thyroid stimulating hormone increased	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigations	Blood thyroid stimulating hormone increased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Blood thyroid stimulating hormone increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	White blood cell count decreased		3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	White blood cell count decreased	Mild	3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	White blood cell count decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	White blood cell count decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Aspartate aminotransferase increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Aspartate aminotransferase increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Aspartate aminotransferase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Aspartate aminotransferase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood urea increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood urea increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood urea increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood urea increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Electrocardiogram T wave peaked		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram T wave peaked	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram T wave peaked	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram T wave peaked	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Tri-iodothyronine free increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Tri-iodothyronine free increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Tri-iodothyronine free increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Tri-iodothyronine free increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron decreased		0%	7.1% (1.0, 37.0)	P=1.000, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Blood iron decreased	Mild	0%	7.1% (1.0, 37.0)	P=1.000, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.069 (-0.203 - 0.064)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood iron decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine decreased		0%	7.1% (1.0, 37.0)	P=1.000, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Thyroxine decreased	Mild	0%	7.1% (1.0, 37.0)	P=1.000, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.069 (-0.203 - 0.064)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Thyroxine decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Transaminases increased		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Transaminases increased	Mild	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Transaminases increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Transaminases increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Blood cholesterol increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood lactate dehydrogenase increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood lactate dehydrogenase increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Blood lactate dehydrogenase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood lactate dehydrogenase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood potassium increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood potassium increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Blood potassium increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood potassium increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood pressure increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood pressure increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood pressure increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Blood pressure increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram ST segment abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram ST segment abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram ST segment abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Electrocardiogram ST segment abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram high voltage		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram high voltage	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram high voltage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram high voltage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Haemoglobin decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Haemoglobin decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Haemoglobin decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Haemoglobin decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Hepatic enzyme abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Hepatic enzyme increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Lipids increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Lipids increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Investigation s	Lipids increased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Lipids increased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Basophil count increased		3.0% (0.4, 18.6)	0%	P=0.185 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Basophil count increased	Mild	3.0% (0.4, 18.6)	0%	P=0.185 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Basophil count increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Basophil count increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Liver function test abnormal		0%	7.1% (1.0, 37.0)	P=1.000, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%							
Investigations	Liver function test abnormal	Mild	0%	7.1% (1.0, 37.0)	P=1.000, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.075 (-0.213 - 0.063)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Investigation s	Liver function test abnormal	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Liver function test abnormal	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Thyroid function test abnormal		0%	7.1% (1.0, 37.0)	P=1.000 , I <sup>2</sup> =0%	P=0.138 , I <sup>2</sup> =0%							
Investigation s	Thyroid function test abnormal	Mild	0%	7.1% (1.0, 37.0)	P=1.000 , I <sup>2</sup> =0%	P=0.138 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.075 (-0.213 - 0.063)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Thyroid function test abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroid function test abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cortisol decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cortisol decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Blood cortisol decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cortisol decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol free urine decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol free urine decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Cortisol free urine decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol free urine decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine free decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine free decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine free decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Investigations	Thyroxine free decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders			30.3% (17.1, 47.7)	7.1% (1.0, 37.0)	P=0.852, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders		Mild	27.3% (14.8, 44.7)	7.1% (1.0, 37.0)	P=0.886, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%	4.654 (0.528, 41.027)	3.610 (0.538, 24.231)	0.196 (-0.009 - 0.402)	P=0.373, I <sup>2</sup> =0%	P=0.326, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Respiratory, thoracic and mediastinal disorders		Moderate	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Cough		27.3% (14.8, 44.7)	0%	P=0.886, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Cough	Mild	27.3% (14.8, 44.7)	0%	P=0.886, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.272 (0.119 - 0.424)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.610, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Cough	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Cough	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Asthma		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Asthma	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Asthma	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Asthma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal congestion		0%	7.1% (1.0, 37.0)	P=1.000 , I <sup>2</sup> =0%	P=0.138 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Mild	0%	7.1% (1.0, 37.0)	P=1.000 , I <sup>2</sup> =0%	P=0.138 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.075 (-0.213 - 0.063)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Epistaxis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Epistaxis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Epistaxis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Epistaxis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Respiratory disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sinus congestion		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Allergic cough		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Allergic cough	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Allergic cough	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Allergic cough	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Wheezing		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Wheezing	Mild	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Wheezing	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Wheezing	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Laryngospasm		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Moderate	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Nasal obstruction		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Productive cough		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Productive cough	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Productive cough	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Respiratory, thoracic and mediastinal disorders	Productive cough	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions			27.3% (14.8, 44.7)	7.1% (1.0, 37.0)	P=0.514, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions		Mild	27.3% (14.8, 44.7)	7.1% (1.0, 37.0)	P=0.514, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%	4.422 (0.540, 36.197)	3.689 (0.540, 25.217) 0.183	0.202 (-0.009 - 0.414)	P=0.237, I <sup>2</sup> =283 9%	P=0.206, I <sup>2</sup> =374 8%	P=0.286, I <sup>2</sup> =122 1%	
General disorders and administration site conditions		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
General disorders and administrati on site conditions	Pyrexia		21.2% (10.5, 38.3)	7.1% (1.0, 37.0)	P=0.979 , I <sup>2</sup> =0%	P=0.138 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Pyrexia	Mild	21.2% (10.5, 38.3)	7.1% (1.0, 37.0)	P=0.979 , I <sup>2</sup> =0%	P=0.138 , I <sup>2</sup> =0%	3.312 (0.372, 29.482)	2.816 (0.407, 19.498) 0.294	0.137 (-0.060 - 0.334)	P=0.35 8, I <sup>2</sup> =0%	P=0.32 1, I <sup>2</sup> =0%	P=0.50 3, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Pyrexia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Pyrexia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Injection site pruritus		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site pruritus	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site pruritus	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Injection site pruritus	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site pain		3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Injection site pain	Mild	3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Injection site pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
General disorders and administrati on site conditions	Injection site pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site swelling		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site swelling	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
General disorders and administrati on site conditions	Injection site swelling	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site swelling	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Injection site erythema		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site erythema	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Injection site erythema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site erythema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site reaction		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Injection site reaction	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site reaction	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Injection site reaction	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site urticaria		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Injection site urticaria	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site urticaria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site urticaria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Medical device discomfort		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Medical device discomfort	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Medical device discomfort	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Medical device discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Vaccination site pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Vaccination site pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Vaccination site pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Vaccination site pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Fatigue		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Fatigue	Mild	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Fatigue	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
General disorders and administrati on site conditions	Fatigue	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Gait disturbance		3.0% (0.4, 18.6)	0%	P=0.288 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Gait disturbance	Mild	3.0% (0.4, 18.6)	0%	P=0.288 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Gait disturbance	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Gait disturbance	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Injection site atrophy		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site atrophy	Mild	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Injection site atrophy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site atrophy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site bruising		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
General disorders and administrati on site conditions	Injection site bruising	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site bruising	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Injection site bruising	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site haemorrhage		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Injection site haemorrhage	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site haemorrhage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site haemorrhage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Peripheral swelling		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Peripheral swelling	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Peripheral swelling	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Peripheral swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Face oedema		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Face oedema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Face oedema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
General disorders and administrati on site conditions	Face oedema	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Influenza like illness		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Influenza like illness	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
General disorders and administration site conditions	Influenza like illness	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Influenza like illness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Gastrointesti nal disorders			15.2% (6.5, 31.6)	14.3% (3.6, 42.7)	P=0.905 , I <sup>2</sup> =0%	P=0.029 , I <sup>2</sup> =0%							
Gastrointesti nal disorders		Mild	15.2% (6.5, 31.6)	14.3% (3.6, 42.7)	P=0.905 , I <sup>2</sup> =0%	P=0.029 , I <sup>2</sup> =0%	1.013 (0.178, 5.774)	1.011 (0.235, 4.357) 0.988	0.002 (-0.224 - 0.227)	P=0.14 2, I <sup>2</sup> =537 1%	P=0.13 7, I <sup>2</sup> =547 3%	P=0.11 7, I <sup>2</sup> =591 9%	
Gastrointesti nal disorders		Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Diarrhoea		3.0% (0.4, 18.6)	0%	P=0.185 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Gastrointestinal disorders	Diarrhoea	Mild	3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Diarrhoea	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Diarrhoea	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Vomiting		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Gastrointesti nal disorders	Vomiting	Mild	3.0% (0.4, 18.6)	0%	P=0.288 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
Gastrointesti nal disorders	Vomiting	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Vomiting	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Nausea		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Gastrointesti nal disorders	Nausea	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Nausea	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Nausea	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Abdominal pain upper		3.0% (0.4, 18.6)	0%	P=0.185 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Abdominal pain upper	Mild	3.0% (0.4, 18.6)	0%	P=0.185 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Gastrointestinal disorders	Abdominal pain upper	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal pain upper	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal pain		3.0% (0.4, 18.6)	7.1% (1.0, 37.0)	P=0.288, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal pain	Mild	3.0% (0.4, 18.6)	7.1% (1.0, 37.0)	P=0.288, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%	0.436 (0.030, 6.295)	0.436 (0.033, 5.786) 0.529	-0.042 (-0.197, -0.112)	P=0.261, I <sup>2</sup> =2085%	P=0.277, I <sup>2</sup> =1550%	P=0.227, I <sup>2</sup> =3161%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Gastrointestinal disorders	Abdominal pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Dyspepsia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Dyspepsia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Dyspepsia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Gastrointestinal disorders	Dyspepsia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Constipation		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Constipation	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Constipation	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Gastrointestinal disorders	Constipation	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Toothache		0%	7.1% (1.0, 37.0)	P=1.000, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%							
Gastrointestinal disorders	Toothache	Mild	0%	7.1% (1.0, 37.0)	P=1.000, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.075 (-0.213 - 0.063)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Toothache	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Toothache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Gastrointestinal disorders	Abdominal discomfort		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal discomfort	Mild	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Abdominal discomfort	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Gastrointestinal disorders	Enteritis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Enteritis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Enteritis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Enteritis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastrointestinal disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Gastrointestinal disorders	Gastrointestinal disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastrointestinal disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastrointestinal disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Aphthous ulcer		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Gastrointestinal disorders	Aphthous ulcer	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Aphthous ulcer	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Aphthous ulcer	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastric disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastric disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Gastrointestinal disorders	Gastric disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastric disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Lip swelling		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Lip swelling	Mild	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Lip swelling	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Gastrointestinal disorders	Lip swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal distension		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal distension	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal distension	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Gastrointesti nal disorders	Abdominal distension	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Noninfective gingivitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Noninfective gingivitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Noninfective gingivitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Noninfective gingivitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Gastrointesti nal disorders	Gastrointesti nal motility disorder		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastrointesti nal motility disorder	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastrointesti nal motility disorder	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastrointesti nal motility disorder	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Nervous system disorders			12.1% (4.6, 28.2)	7.1% (1.0, 37.0)	P=0.028 , I <sup>2</sup> =0%	P=0.138 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Nervous system disorders		Mild	9.1% (3.0, 24.7)	7.1% (1.0, 37.0)	P=0.060, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%	1.309 (0.146, 11.758)	1.309 (0.154, 11.140) 0.806	0.023 (-0.157 - 0.203)	P=0.101, I <sup>2</sup> =6287%	P=0.107, I <sup>2</sup> =6149%	P=0.108, I <sup>2</sup> =6137%	
Nervous system disorders		Moderate	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Nervous system disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Headache		12.1% (4.6, 28.2)	7.1% (1.0, 37.0)	P=0.028, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Nervous system disorders	Headache	Mild	9.1% (3.0, 24.7)	7.1% (1.0, 37.0)	P=0.060, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%	1.309 (0.146, 11.758)	1.309 (0.154, 11.140) 0.806	0.023 (-0.157, 0.203)	P=0.101, I <sup>2</sup> =6287%	P=0.107, I <sup>2</sup> =6149%	P=0.108, I <sup>2</sup> =6137%	
Nervous system disorders	Headache	Moderate	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028, 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Nervous system disorders	Headache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Dizziness		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Nervous system disorders	Dizziness	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Dizziness	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Dizziness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Post-traumatic headache		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Nervous system disorders	Post-traumatic headache	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Post-traumatic headache	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Post-traumatic headache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Migraine		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Migraine	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Nervous system disorders	Migraine	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Nervous system disorders	Migraine	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Nervous system disorders	Tremor		3.0% (0.4, 18.6)	0%	P=0.288 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Nervous system disorders	Tremor	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Nervous system disorders	Tremor	Moderate	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Nervous system disorders	Tremor	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications			9.1% (3.0, 24.7)	0%	P=0.735, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications		Mild	6.1% (1.5, 21.2)	0%	P=0.824, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.060 (-0.022 - 0.141)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.620, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Injury, poisoning and procedural complications		Moderate	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Injury, poisoning and procedural complications	Head injury		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Head injury	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Head injury	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Injury, poisoning and procedural complications	Head injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Arthropod bite		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Arthropod bite	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Injury, poisoning and procedural complications	Arthropod bite	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Arthropod bite	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Post-traumatic pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Injury, poisoning and procedural complications	Post-traumatic pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Post-traumatic pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Post-traumatic pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Injury, poisoning and procedural complications	Contusion		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Contusion	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Injury, poisoning and procedural complications	Contusion	Moderate	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Contusion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ligament sprain		3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Injury, poisoning and procedural complications	Ligament sprain	Mild	3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Ligament sprain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ligament sprain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Injury, poisoning and procedural complications	Skin laceration		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Skin laceration	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Skin laceration	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Injury, poisoning and procedural complications	Skin laceration	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal bite		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal bite	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Injury, poisoning and procedural complications	Animal bite	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal bite	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Injury, poisoning and procedural complications	Ankle fracture		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ankle fracture	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ankle fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Injury, poisoning and procedural complications	Ankle fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns second degree		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns second degree	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Injury, poisoning and procedural complications	Burns second degree	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns second degree	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Face injury		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Injury, poisoning and procedural complications	Face injury	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Face injury	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Face injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Injury, poisoning and procedural complications	Fall		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Fall	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Injury, poisoning and procedural complications	Fall	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Fall	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Laceration		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Injury, poisoning and procedural complications	Laceration	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Laceration	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Laceration	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Injury, poisoning and procedural complications	Meniscus injury		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Meniscus injury	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Meniscus injury	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Injury, poisoning and procedural complications	Meniscus injury	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Muscle strain		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Muscle strain	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Injury, poisoning and procedural complications	Muscle strain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Muscle strain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Injury, poisoning and procedural complications	Thermal burn		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Thermal burn	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Thermal burn	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Injury, poisoning and procedural complications	Thermal burn	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Wrist fracture		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Wrist fracture	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Injury, poisoning and procedural complications	Wrist fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Wrist fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Radius fracture		3.0% (0.4, 18.6)	0%	P=0.288 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Injury, poisoning and procedural complications	Radius fracture	Mild	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Radius fracture	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Radius fracture	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Injury, poisoning and procedural complications	Animal scratch		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal scratch	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Injury, poisoning and procedural complications	Animal scratch	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal scratch	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Eye injury		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Injury, poisoning and procedural complications	Eye injury	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Eye injury	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Eye injury	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Injury, poisoning and procedural complications	Joint injury		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Joint injury	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Joint injury	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Injury, poisoning and procedural complications	Joint injury	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns first degree		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns first degree	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Injury, poisoning and procedural complications	Burns first degree	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns first degree	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Injury, poisoning and procedural complications	Concussion		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Concussion	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Concussion	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Injury, poisoning and procedural complications	Concussion	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Upper limb fracture		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Upper limb fracture	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Injury, poisoning and procedural complications	Upper limb fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Upper limb fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders			9.1% (3.0, 24.7)	14.3% (3.6, 42.7)	P=0.375 , I <sup>2</sup> =0%	P=0.655 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Skin and subcutaneous tissue disorders		Mild	9.1% (3.0, 24.7)	7.1% (1.0, 37.0)	P=0.375, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%	1.176 (0.106, 13.033)	1.151 (0.146, 9.088) 0.894	0.011 (-0.152, 0.175)	P=0.654, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	P=0.710, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders		Moderate	0%	7.1% (1.0, 37.0)	P=1.000, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.069 (-0.203, 0.064)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash		0%	7.1% (1.0, 37.0)	P=1.000, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Skin and subcutaneous tissue disorders	Rash	Mild	0%	7.1% (1.0, 37.0)	P=1.000, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.075 (-0.213 - 0.063)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Rash	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Skin and subcutaneous tissue disorders	Dermatitis allergic		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis allergic	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Skin and subcutaneous tissue disorders	Urticaria		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Skin and subcutaneous tissue disorders	Urticaria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Eczema		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Eczema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Eczema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Skin and subcutaneous tissue disorders	Eczema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis contact		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis contact	Mild	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Skin and subcutaneous tissue disorders	Dermatitis contact	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis contact	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria papular		3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria papular	Mild	3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Skin and subcutaneous tissue disorders	Urticaria papular	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria papular	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Cafe au lait spots		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Skin and subcutaneous tissue disorders	Cafe au lait spots	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Cafe au lait spots	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Cafe au lait spots	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Keratosis pilaris		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Skin and subcutaneous tissue disorders	Keratosis pilaris	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Keratosis pilaris	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Keratosis pilaris	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Skin and subcutaneous tissue disorders	Pityriasis alba		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Pityriasis alba	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Pityriasis alba	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Pityriasis alba	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Skin and subcutaneous tissue disorders	Rash erythematous		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash erythematous	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash erythematous	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Skin and subcutaneous tissue disorders	Rash erythematous	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash pruritic		0%	7.1% (1.0, 37.0)	P=1.000, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash pruritic	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash pruritic	Moderate	0%	7.1% (1.0, 37.0)	P=1.000, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.069 (-0.203 - 0.064)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Skin and subcutaneous tissue disorders	Rash pruritic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Skin and subcutaneous tissue disorders	Dermatitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dyshidrotic eczema		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria chronic		3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Skin and subcutaneous tissue disorders	Urticaria chronic	Mild	3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Urticaria chronic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria chronic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Petechiae		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Skin and subcutaneous tissue disorders	Petechiae	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Petechiae	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Petechiae	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Musculoskeletal and connective tissue disorders			3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders		Mild	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Musculoskeletal and connective tissue disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Pain in extremity		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Pain in extremity	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Musculoskeletal and connective tissue disorders	Pain in extremity	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Pain in extremity	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatotropin Mean (95%CI)	Daily somatotropin Mean (95%CI)	Lonapeg somatotropin	Daily somatotropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Musculoskeletal and connective tissue disorders	Arthralgia		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthralgia	Mild	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders	Arthralgia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Musculoskeletal and connective tissue disorders	Arthralgia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Musculoskeletal pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Musculoskeletal and connective tissue disorders	Neck pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Musculoskeletal and connective tissue disorders	Arthritis reactive		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthritis reactive	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Musculoskeletal and connective tissue disorders	Arthritis reactive	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthritis reactive	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Back pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Musculoskeletal and connective tissue disorders	Back pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Back pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Back pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Musculoskeletal and connective tissue disorders	Neck mass		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck mass	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck mass	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Musculoskeletal and connective tissue disorders	Neck mass	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Pain in jaw		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Pain in jaw	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Musculoskeletal and connective tissue disorders	Pain in jaw	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Pain in jaw	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Musculoskeletal and connective tissue disorders	Synovial cyst		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Synovial cyst	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Synovial cyst	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Musculoskeletal and connective tissue disorders	Synovial cyst	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Scoliosis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Scoliosis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Musculoskeletal and connective tissue disorders	Scoliosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Scoliosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders			3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Metabolism and nutrition disorders		Mild	3.0% (0.4, 18.6)	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypertriglyceridaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Metabolism and nutrition disorders	Hypertriglyceridaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypertriglyceridaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypertriglyceridaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Metabolism and nutrition disorders	Hypercholesterolaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypercholesterolaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypercholesterolaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypercholesterolaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Metabolism and nutrition disorders	Decreased appetite		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Decreased appetite	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Decreased appetite	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Metabolism and nutrition disorders	Decreased appetite	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperuricae mia		3.0% (0.4, 18.6)	0%	P=0.185 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperuricae mia	Mild	3.0% (0.4, 18.6)	0%	P=0.185 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Hyperuricae mia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Metabolism and nutrition disorders	Hyperuricaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Polydipsia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Polydipsia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Metabolism and nutrition disorders	Polydipsia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Polydipsia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Calcium deficiency		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Calcium deficiency	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Metabolism and nutrition disorders	Calcium deficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Calcium deficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperglycaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Metabolism and nutrition disorders	Hyperglycae mia	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperglycae mia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperglycae mia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperlipidae mia		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Metabolism and nutrition disorders	Hyperlipidaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperlipidaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperlipidaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Eye disorders			9.1% (3.0, 24.7)	28.6% (11.1, 56.1)	P=0.375, I <sup>2</sup> =0%	P=0.485, I <sup>2</sup> =0%							
Eye disorders		Mild	9.1% (3.0, 24.7)	28.6% (11.1, 56.1)	P=0.375, I <sup>2</sup> =0%	P=0.485, I <sup>2</sup> =0%	0.222 (0.040, 1.238)	0.299 (0.077, 1.162) 0.081	-0.203 (-0.456, 0.050)	P=0.887, I <sup>2</sup> =0%	P=0.772, I <sup>2</sup> =0%	P=0.749, I <sup>2</sup> =0%	
Eye disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Refraction disorder		3.0% (0.4, 18.6)	7.1% (1.0, 37.0)	P=0.185, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Eye disorders	Refraction disorder	Mild	3.0% (0.4, 18.6)	7.1% (1.0, 37.0)	P=0.185, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%	0.308 (0.015, 6.117)	0.357 (0.027, 4.699) 0.434	-0.048 (-0.193, 0.096)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Refraction disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Refraction disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Conjunctivitis allergic		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Eye disorders	Conjunctivit is allergic	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Conjunctivit is allergic	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Conjunctivit is allergic	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Eye swelling		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Eye swelling	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Eye disorders	Eye swelling	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Eye swelling	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Strabismus		0%	7.1% (1.0, 37.0)	P=1.000 , I <sup>2</sup> =0%	P=0.336 , I <sup>2</sup> =0%							
Eye disorders	Strabismus	Mild	0%	7.1% (1.0, 37.0)	P=1.000 , I <sup>2</sup> =0%	P=0.336 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.069 (-0.203 - 0.064)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Eye disorders	Strabismus	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Strabismus	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Myopia		0%	7.1% (1.0, 37.0)	P=1.000 , I <sup>2</sup> =0%	P=0.336 , I <sup>2</sup> =0%							
Eye disorders	Myopia	Mild	0%	7.1% (1.0, 37.0)	P=1.000 , I <sup>2</sup> =0%	P=0.336 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.069 (-0.203 - 0.064)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Eye disorders	Myopia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Myopia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye haemorrhage		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye haemorrhage	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye haemorrhage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Eye disorders	Eye haemorrhage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Astigmatism		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Astigmatism	Mild	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Astigmatism	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Eye disorders	Astigmatism	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Corneal epithelium defect		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Corneal epithelium defect	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Corneal epithelium defect	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Corneal epithelium defect	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Eye disorders	Eye pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Xerophthalmia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Eye disorders	Xerophthal mia	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Xerophthal mia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Xerophthal mia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Vernal keratoconjun ctivitis		0%	7.1% (1.0, 37.0)	P=1.000 , I <sup>2</sup> =0%	P=0.138 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Eye disorders	Vernal keratoconjunctivitis	Mild	0%	7.1% (1.0, 37.0)	P=1.000, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.075 (-0.213 - 0.063)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Vernal keratoconjunctivitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Vernal keratoconjunctivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Vitreous opacities		3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Eye disorders	Vitreous opacities	Mild	3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Vitreous opacities	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Vitreous opacities	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Hypermetro pia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Hypermetro pia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Eye disorders	Hypermetropia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Hypermetropia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Papilloedema		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Papilloedema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Papilloedema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Eye disorders	Papilloedema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders			6.1% (1.5, 21.2)	0%	P=0.129, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders		Mild	6.1% (1.5, 21.2)	0%	P=0.129, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.066 (-0.019 - 0.150)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Blood and lymphatic system disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenopathy		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenopathy	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Blood and lymphatic system disorders	Lymphadenopathy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenopathy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Anaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Blood and lymphatic system disorders	Anaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Neutropenia		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Blood and lymphatic system disorders	Neutropenia	Mild	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Neutropenia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Neutropenia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Blood and lymphatic system disorders	Granulocytopenia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Granulocytopenia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Granulocytopenia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Granulocytopenia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Blood and lymphatic system disorders	Lymphadenitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Blood and lymphatic system disorders	Lymphadenitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Iron deficiency anaemia		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Iron deficiency anaemia	Mild	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Iron deficiency anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Blood and lymphatic system disorders	Iron deficiency anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Thymus disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Thymus disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Blood and lymphatic system disorders	Thymus disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Thymus disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Hypochromic anaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Hypochromic anaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Blood and lymphatic system disorders	Hypochromic anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Hypochromic anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders			3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders		Mild	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Immune system disorders		Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Immune system disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Immune system disorders	Seasonal allergy		3.0% (0.4, 18.6)	0%	P=0.288 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Immune system disorders	Seasonal allergy	Mild	3.0% (0.4, 18.6)	0%	P=0.288 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Immune system disorders	Seasonal allergy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Seasonal allergy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Hypersensitivity		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Hypersensitivity	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Hypersensitivity	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Immune system disorders	Hypersensitivity	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Allergy to animal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Allergy to animal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Allergy to animal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Immune system disorders	Allergy to animal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Food allergy		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Food allergy	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Food allergy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Food allergy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Endocrine disorders			6.1% (1.5, 21.2)	7.1% (1.0, 37.0)	P=0.824 , I <sup>2</sup> =0%	P=0.138 , I <sup>2</sup> =0%							
Endocrine disorders		Mild	3.0% (0.4, 18.6)	7.1% (1.0, 37.0)	P=0.185 , I <sup>2</sup> =0%	P=0.138 , I <sup>2</sup> =0%	0.308 (0.015, 6.117)	0.357 (0.027, 4.699) 0.434	-0.048 (-0.193 - 0.096)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
Endocrine disorders		Moderate	3.0% (0.4, 18.6)	0%	P=0.288 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
Endocrine disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Endocrine disorders	Secondary hypothyroidism		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Endocrine disorders	Secondary hypothyroidism	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Endocrine disorders	Secondary hypothyroidism	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Endocrine disorders	Secondary hypothyroidism	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Endocrine disorders	Hypothyroidism		3.0% (0.4, 18.6)	0%	P=0.185 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Endocrine disorders	Hypothyroidism	Mild	3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Hypothyroidism	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Hypothyroidism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Adrenal insufficiency		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Endocrine disorders	Adrenal insufficiency	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Adrenal insufficiency	Moderate	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Adrenal insufficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Precocious puberty		0%	7.1% (1.0, 37.0)	P=1.000, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Endocrine disorders	Precocious puberty	Mild	0%	7.1% (1.0, 37.0)	P=1.000 , I <sup>2</sup> =0%	P=0.138 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.075 (-0.213 - 0.063)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Endocrine disorders	Precocious puberty	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Endocrine disorders	Precocious puberty	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Endocrine disorders	Diabetes insipidus		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Endocrine disorders	Diabetes insipidus	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Endocrine disorders	Diabetes insipidus	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Endocrine disorders	Diabetes insipidus	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Endocrine disorders	Secondary adrenocortic al insufficiency		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Endocrine disorders	Secondary adrenocortic al insufficiency	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Endocrine disorders	Secondary adrenocortical insufficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Secondary adrenocortical insufficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders			6.1% (1.5, 21.2)	0%	P=0.058, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders		Mild	6.1% (1.5, 21.2)	0%	P=0.058, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.054 (-0.024 - 0.131)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Reproductiv e system and breast disorders		Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Penile adhesion		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Penile adhesion	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Reproductive system and breast disorders	Penile adhesion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Penile adhesion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Gynaecomastia		3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Reproductiv e system and breast disorders	Gynaecomasia	Mild	3.0% (0.4, 18.6)	0%	P=0.185 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
Reproductiv e system and breast disorders	Gynaecomasia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Gynaecomasia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Genital discomfort		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Reproductiv e system and breast disorders	Genital discomfort	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Genital discomfort	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Genital discomfort	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Reproductiv e system and breast disorders	Pelvic fluid collection		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Pelvic fluid collection	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Pelvic fluid collection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Pelvic fluid collection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Reproductive system and breast disorders	Testicular appendage torsion		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Testicular appendage torsion	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Testicular appendage torsion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Reproductiv e system and breast disorders	Testicular appendage torsion	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Balanoposth itis		3.0% (0.4, 18.6)	0%	P=0.185 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Balanoposth itis	Mild	3.0% (0.4, 18.6)	0%	P=0.185 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
Reproductiv e system and breast disorders	Balanoposth itis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Reproductive system and breast disorders	Balanoposthitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders			3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders		Mild	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Ear and labyrinth disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Ear and labyrinth disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Ear pain		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Ear pain	Mild	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Ear and labyrinth disorders	Ear pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Ear and labyrinth disorders	Ear pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Cerumen impaction		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Cerumen impaction	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Cerumen impaction	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Cerumen impaction	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Ear and labyrinth disorders	Motion sickness		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Motion sickness	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Motion sickness	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Motion sickness	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Psychiatric disorders			3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders		Moderate	3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Psychiatric disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Attention deficit/hyperactivity disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Psychiatric disorders	Attention deficit/hyperactivity disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Attention deficit/hyperactivity disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Attention deficit/hyperactivity disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Affect lability		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Psychiatric disorders	Affect lability	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Psychiatric disorders	Affect lability	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Psychiatric disorders	Affect lability	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Psychiatric disorders	Enuresis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Psychiatric disorders	Enuresis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Psychiatric disorders	Enuresis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Enuresis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Depressive symptom		3.0% (0.4, 18.6)	0%	P=0.288, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Depressive symptom	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Psychiatric disorders	Depressive symptom	Moderate	3.0% (0.4, 18.6)	0%	P=0.288 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Psychiatric disorders	Depressive symptom	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders			0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders		Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders		Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Cardiac disorders	Sinoatrial block		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinoatrial block	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinoatrial block	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinoatrial block	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Cardiac disorders	Sinus tachycardia		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Sinus tachycardia	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Sinus tachycardia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Sinus tachycardia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Tachycardia		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Cardiac disorders	Tachycardia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Tachycardia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Tachycardia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Myocarditis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Myocarditis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Cardiac disorders	Myocarditis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Myocarditis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Wandering pacemaker		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Wandering pacemaker	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Cardiac disorders	Wandering pacemaker	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Wandering pacemaker	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Renal and urinary disorders			0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Renal and urinary disorders		Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Renal and urinary disorders		Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Renal and urinary disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Pollakiuria		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Pollakiuria	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Pollakiuria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Pollakiuria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Renal and urinary disorders	Polyuria		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Polyuria	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Polyuria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Polyuria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Renal and urinary disorders	Nocturia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Nocturia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Nocturia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Nocturia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Vascular disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Hypotension		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Hypotension	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Vascular disorders	Hypotension	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Hypotension	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Cyanosis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Cyanosis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Isolated organic													
Vascular disorders	Cyanosis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Vascular disorders	Cyanosis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Congenital, familial and genetic disorders			3.0% (0.4, 18.6)	0%	P=0.185 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Congenital, familial and genetic disorders		Mild	3.0% (0.4, 18.6)	0%	P=0.185 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Congenital, familial and genetic disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Supernumerary teeth		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Supernumerary teeth	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Congenital, familial and genetic disorders	Supernumerary teeth	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Supernumerary teeth	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Buried penis syndrome		3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Congenital, familial and genetic disorders	Buried penis syndrome	Mild	3.0% (0.4, 18.6)	0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Congenital, familial and genetic disorders	Buried penis syndrome	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Buried penis syndrome	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders			0%	7.1% (1.0, 37.0)	P=1.000, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Hepatobiliary disorders		Mild	0%	7.1% (1.0, 37.0)	P=1.000, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.069 (-0.203 - 0.064)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Hepatobiliary disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders	Hepatomegaly		0%	7.1% (1.0, 37.0)	P=1.000, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic													
Hepatobiliary disorders	Hepatomegaly	Mild	0%	7.1% (1.0, 37.0)	P=1.000, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.069 (-0.203 - 0.064)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Hepatobiliary disorders	Hepatomegaly	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders	Hepatomegaly	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Any adverse event			81.0% (58.8, 92.7)	90.9% (56.1, 98.7)	P=0.240, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Any adverse event		Mild	61.9% (40.2, 79.7)	36.4% (14.3, 66.1)	P=0.075, I <sup>2</sup> =0%	P=0.138, I <sup>2</sup> =0%	2.917 (0.565, 15.054)	1.613 (0.727, 3.579) 0.239	0.229 (-0.106, 0.564)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Any adverse event		Moderate	19.0% (7.3, 41.2)	54.5% (26.8, 79.7)	P=0.240, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	0.190 (0.035, 1.026)	0.370 (0.136, 1.008) 0.052	-0.338 (-0.672, -0.005)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Any adverse event		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations			38.1% (20.3, 59.8)	63.6% (33.9, 85.7)	P=0.075 , I <sup>2</sup> =0%	P=0.138 , I <sup>2</sup> =0%							
Infections and infestations		Mild	23.8% (10.3, 46.0)	36.4% (14.3, 66.1)	P=0.182 , I <sup>2</sup> =0%	P=0.327 , I <sup>2</sup> =0%	0.577 (0.113, 2.951)	0.694 (0.240, 2.012) 0.502	-0.109 (-0.441 - 0.222)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Infections and infestations		Moderate	14.3% (4.7, 36.1)	27.3% (9.0, 58.6)	P=0.316 , I <sup>2</sup> =0%	P=0.412 , I <sup>2</sup> =0%	0.467 (0.075, 2.923)	0.556 (0.137, 2.256) 0.411	-0.119 (-0.420 - 0.181)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Upper respiratory tract infection		0%	9.1% (1.3, 43.9)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%							
Infections and infestations	Upper respiratory tract infection	Mild	0%	9.1% (1.3, 43.9)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Upper respiratory tract infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Upper respiratory tract infection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Nasopharyngitis		0%	9.1% (1.3, 43.9)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%							
Infections and infestations	Nasopharyngitis	Mild	0%	9.1% (1.3, 43.9)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Infections and infestations	Nasopharyngitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Infections and infestations	Nasopharyngitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis		0%	45.5% (20.3, 73.2)	P=1.000, I <sup>2</sup> =0%	P=0.255, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis	Mild	0%	45.5% (20.3, 73.2)	P=1.000, I <sup>2</sup> =0%	P=0.255, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.448 (-0.744 - -0.152)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pharyngitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Infections and infestations	Pharyngitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Bronchitis		4.8% (0.7, 27.1)	18.2% (4.6, 50.7)	P=0.574, I <sup>2</sup> =0%	P=0.515, I <sup>2</sup> =0%							
Infections and infestations	Bronchitis	Mild	4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Bronchitis	Moderate	0%	18.2% (4.6, 50.7)	P=1.000, I <sup>2</sup> =0%	P=0.515, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.179 (-0.406 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Infections and infestations	Bronchitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection		19.0% (7.3, 41.2)	18.2% (4.6, 50.7)	P=0.240, I <sup>2</sup> =0%	P=0.515, I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection	Mild	14.3% (4.7, 36.1)	9.1% (1.3, 43.9)	P=0.316, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	1.800 (0.162, 20.028)	1.667 (0.199, 13.984) 0.638	0.060 (-0.166, 0.286)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Respiratory tract infection	Moderate	4.8% (0.7, 27.1)	9.1% (1.3, 43.9)	P=0.574, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	0.529 (0.030, 9.499)	0.556 (0.039, 7.957) 0.665	-0.040 (-0.232, 0.153)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Respiratory tract infection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Infections and infestations	Rhinitis		4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rhinitis	Mild	4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Rhinitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rhinitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Infections and infestations	Pharyngitis streptococcal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis streptococcal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis streptococcal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis streptococcal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinusitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Sinusitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Sinusitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Sinusitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis		0%	18.2% (4.6, 50.7)	P=1.000 , I <sup>2</sup> =0%	P=0.515 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Infections and infestations	Gastroenteritis	Mild	0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Gastroenteritis	Moderate	0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Gastroenteritis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Ear infection		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Ear infection	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Ear infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Ear infection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pneumonia		0%	18.2% (4.6, 50.7)	P=1.000 , I <sup>2</sup> =0%	P=0.515 , I <sup>2</sup> =0%							
Infections and infestations	Pneumonia	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Infections and infestations	Pneumonia	Moderate	0%	18.2% (4.6, 50.7)	P=1.000, I <sup>2</sup> =0%	P=0.515, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.179 (-0.406 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pneumonia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Infections and infestations	Conjunctivitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis viral		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis viral	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis viral	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Infections and infestations	Gastroenteritis viral	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis media acute		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis media acute	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis media acute	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis media acute	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Infections and infestations	Viral infection		9.5% (2.4, 31.1)	0%	P=0.420, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral infection	Mild	4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.050 (-0.044 - 0.143)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Viral infection	Moderate	4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.050 (-0.044 - 0.143)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Viral infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Varicella		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Varicella	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Varicella	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Varicella	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Respiratory tract infection viral		4.8% (0.7, 27.1)	9.1% (1.3, 43.9)	P=0.574, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection viral	Mild	0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Respiratory tract infection viral	Moderate	4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Respiratory tract infection viral	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Enteritis infectious		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Enteritis infectious	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Enteritis infectious	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Enteritis infectious	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Influenza		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Influenza	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Influenza	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Influenza	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis media		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Otitis media	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis media	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis media	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Periodontitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Periodontitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Periodontitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Periodontitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Herpangina		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Herpangina	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Infections and infestations	Herpangina	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Herpangina	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Helminthic infection		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Helminthic infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Helminthic infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Helminthic infection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pharyngoton sillitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pharyngoton sillitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pharyngoton sillitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pharyngoton sillitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Hordeolum		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Hordeolum	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Hordeolum	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Hordeolum	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Pulpitis dental		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pulpitis dental	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pulpitis dental	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Pulpitis dental	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Urinary tract infection		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Urinary tract infection	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Urinary tract infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Urinary tract infection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Viral upper respiratory tract infection		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Infections and infestations	Viral upper respiratory tract infection	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral upper respiratory tract infection	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral upper respiratory tract infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Laryngitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Laryngitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Laryngitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Laryngitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Oral herpes		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Oral herpes	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Oral herpes	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Oral herpes	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Hand-foot-and-mouth disease		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Hand-foot-and-mouth disease	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Infections and infestations	Hand-foot-and-mouth disease	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hand-foot-and-mouth disease	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Appendicitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Appendicitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Appendicitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Appendicitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Atypical pneumonia		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Atypical pneumonia	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Atypical pneumonia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Atypical pneumonia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Infections and infestations	Conjunctivitis bacterial		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis bacterial	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis bacterial	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis bacterial	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Cystitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Cystitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Cystitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Cystitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Enterobiasis		4.8% (0.7, 27.1)	9.1% (1.3, 43.9)	P=0.574 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Infections and infestations	Enterobiasis	Mild	4.8% (0.7, 27.1)	9.1% (1.3, 43.9)	P=0.574, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	0.529 (0.030, 9.499)	0.556 (0.039, 7.957) 0.665	-0.040 (-0.232, 0.153)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Enterobiasis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Enterobiasis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Infected bite		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Infected bite	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Infected bite	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Infected bite	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Molluscum contagiosum		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Molluscum contagiosum	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Molluscum contagiosum	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Molluscum contagiosum	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis externa		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis externa	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Otitis externa	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Otitis externa	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tinea pedis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tinea pedis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tinea pedis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Tinea pedis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tooth abscess		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tooth abscess	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tooth abscess	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tooth abscess	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Vulvitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Vulvitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Vulvitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Vulvitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Croup infectious		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Infections and infestations	Croup infectious	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Croup infectious	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Croup infectious	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Eczema infected		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Eczema infected	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Eczema infected	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Eczema infected	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Abscess limb		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Abscess limb	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Abscess limb	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Abscess limb	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Bacterial infection		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Bacterial infection	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Bacterial infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Infections and infestations	Bacterial infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Chronic sinusitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Chronic sinusitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Chronic sinusitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Chronic sinusitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Chronic tonsillitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Chronic tonsillitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Chronic tonsillitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Chronic tonsillitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Folliculitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Folliculitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Folliculitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Folliculitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Gastrointestinal bacterial infection		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Gastrointestinal bacterial infection	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Gastrointestinal bacterial infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Gastrointestinal bacterial infection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Herpes virus infection		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Herpes virus infection	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Herpes virus infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Herpes virus infection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Infectious mononucleosis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Infectious mononucleosis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Infectious mononucleosis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Infectious mononucleosis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Mumps		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Mumps	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Mumps	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Mumps	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Myringitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Myringitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Myringitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Myringitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Peritonsillar abscess		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Peritonsillar abscess	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Peritonsillar abscess	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Peritonsillar abscess	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Infections and infestations	Sinobronchitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinobronchitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinobronchitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinobronchitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Subcutaneous abscess		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Infections and infestations	Subcutaneous abscess	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Subcutaneous abscess	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Subcutaneous abscess	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis bacterial		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Tonsillitis bacterial	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis bacterial	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis bacterial	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tracheitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tracheitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Tracheitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Tracheitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Laryngitis viral		0%	9.1% (1.3, 43.9)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%							
Infections and infestations	Laryngitis viral	Mild	0%	9.1% (1.3, 43.9)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Infections and infestations	Laryngitis viral	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Laryngitis viral	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Rotavirus infection		4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Infections and infestations	Rotavirus infection	Mild	4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Infections and infestations	Rotavirus infection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Infections and infestations	Rotavirus infection	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations			9.5% (2.4, 31.1)	18.2% (4.6, 50.7)	P=0.197, I <sup>2</sup> =44.1%	P=0.047, I <sup>2</sup> =0%							
Investigations		Mild	9.5% (2.4, 31.1)	18.2% (4.6, 50.7)	P=0.197, I <sup>2</sup> =44.1%	P=0.047, I <sup>2</sup> =0%	0.290 (0.024, 3.568)	0.436 (0.090, 2.113) 0.303	-0.109 (-0.346, 0.127)	P=0.652, I <sup>2</sup> =0%	P=0.800, I <sup>2</sup> =0%	P=0.366, I <sup>2</sup> =0%	
Investigations		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Investigation s		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Insulin-like growth factor increased		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Insulin-like growth factor increased	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Insulin-like growth factor increased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Insulin-like growth factor increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood glucose increased		4.8% (0.7, 27.1)	9.1% (1.3, 43.9)	P=0.040, I <sup>2</sup> =0%	P=0.010, I <sup>2</sup> =0%							
Investigations	Blood glucose increased	Mild	4.8% (0.7, 27.1)	9.1% (1.3, 43.9)	P=0.040, I <sup>2</sup> =0%	P=0.010, I <sup>2</sup> =0%	NA (NA, NA)	0.333 (0.067, 1.652) 0.178	-0.070 (-0.217, 0.078)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood glucose increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Blood glucose increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Low density lipoprotein increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Low density lipoprotein increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Low density lipoprotein increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Low density lipoprotein increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood alkaline phosphatase increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood alkaline phosphatase increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Blood alkaline phosphatase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood alkaline phosphatase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Eosinophil count increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Eosinophil count increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Eosinophil count increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Eosinophil count increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Blood iron increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood phosphorus increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood phosphorus increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood phosphorus increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Blood phosphorus increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood uric acid increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood uric acid increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood uric acid increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood uric acid increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Alanine aminotransferase increased		0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Investigations	Alanine aminotransferase increased	Mild	0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Alanine aminotransferase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Alanine aminotransferase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Cortisol decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood triglycerides increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Blood triglycerides increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood triglycerides increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood triglycerides increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood glucose abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood glucose abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Blood glucose abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood glucose abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood thyroid stimulating hormone increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Investigation s	Blood thyroid stimulating hormone increased	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood thyroid stimulating hormone increased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood thyroid stimulating hormone increased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	White blood cell count decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	White blood cell count decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	White blood cell count decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	White blood cell count decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Aspartate aminotransferase increased		0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Investigations	Aspartate aminotransferase increased	Mild	0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Aspartate aminotransferase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Aspartate aminotransferase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Blood urea increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood urea increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood urea increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood urea increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram T wave peaked		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Electrocardiogram T wave peaked	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram T wave peaked	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram T wave peaked	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Tri-iodothyronine free increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Investigation s	Tri-iodothyronine free increased	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Tri-iodothyronine free increased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Tri-iodothyronine free increased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood iron decreased		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood iron decreased	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Blood iron decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Thyroxine decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Transaminases increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Transaminases increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Transaminases increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Transaminases increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Blood lactate dehydrogenase increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood lactate dehydrogenase increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood lactate dehydrogenase increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Blood lactate dehydrogenase increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood potassium increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood potassium increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood potassium increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood potassium increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Blood pressure increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood pressure increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood pressure increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood pressure increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram ST segment abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Electrocardiogram ST segment abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram ST segment abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram ST segment abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram high voltage		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Electrocardiogram high voltage	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram high voltage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram high voltage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Haemoglobin decreased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Haemoglobin decreased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Haemoglobin decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Haemoglobin decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Hepatic enzyme abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Hepatic enzyme increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Lipids increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Lipids increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Lipids increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Lipids increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Basophil count increased		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Basophil count increased	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Basophil count increased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Basophil count increased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Liver function test abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Liver function test abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Liver function test abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Liver function test abnormal	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Thyroid function test abnormal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroid function test abnormal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroid function test abnormal	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Investigation s	Thyroid function test abnormal	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood cortisol decreased		4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood cortisol decreased	Mild	4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Investigation s	Blood cortisol decreased	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood cortisol decreased	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Cortisol free urine decreased		4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol free urine decreased	Mild	4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Cortisol free urine decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol free urine decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Investigations	Thyroxine free decreased		4.8% (0.7, 27.1)	0%	P=0.040, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine free decreased	Mild	4.8% (0.7, 27.1)	0%	P=0.040, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.035 (-0.044 - 0.114)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Thyroxine free decreased	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine free decreased	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders			14.3% (4.7, 36.1)	18.2% (4.6, 50.7)	P=0.316, I <sup>2</sup> =0%	P=0.515, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders		Mild	9.5% (2.4, 31.1)	9.1% (1.3, 43.9)	P=0.420, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	1.125 (0.089, 14.202)	1.111 (0.114, 10.783) 0.928	0.010 (-0.201, 0.221)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders		Moderate	4.8% (0.7, 27.1)	9.1% (1.3, 43.9)	P=0.574, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	0.529 (0.030, 9.499)	0.556 (0.039, 7.957) 0.665	-0.040 (-0.232, 0.153)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Cough		4.8% (0.7, 27.1)	9.1% (1.3, 43.9)	P=0.574 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Cough	Mild	4.8% (0.7, 27.1)	9.1% (1.3, 43.9)	P=0.574 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%	0.529 (0.030, 9.499)	0.556 (0.039, 7.957) 0.665	-0.040 (-0.232 - 0.153)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Cough	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Cough	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea		0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Mild	0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Asthma		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Asthma	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Asthma	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Asthma	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Nasal congestion		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Epistaxis		4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Epistaxis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Epistaxis	Moderate	4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Epistaxis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Respiratory disorder		4.8% (0.7, 27.1)	9.1% (1.3, 43.9)	P=0.574 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Mild	4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Moderate	0%	9.1% (1.3, 43.9)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sinus congestion		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Allergic cough		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Allergic cough	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Allergic cough	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Allergic cough	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Wheezing		0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Wheezing	Mild	0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Wheezing	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Wheezing	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Laryngospasm		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Nasal obstruction		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Productive cough		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Respiratory, thoracic and mediastinal disorders	Productive cough	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Productive cough	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Productive cough	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
General disorders and administrati on site conditions			4.8% (0.7, 27.1)	18.2% (4.6, 50.7)	P=0.574 , I <sup>2</sup> =0%	P=0.515 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions		Mild	4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions		Moderate	0%	18.2% (4.6, 50.7)	P=1.000, I <sup>2</sup> =0%	P=0.515, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.179 (-0.406 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
General disorders and administrati on site conditions	Pyrexia		4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Pyrexia	Mild	4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
General disorders and administrati on site conditions	Pyrexia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
General disorders and administrati on site conditions	Pyrexia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site pruritus		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
General disorders and administrati on site conditions	Injection site pruritus	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site pruritus	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Injection site pruritus	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Injection site pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Injection site swelling		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site swelling	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Injection site swelling	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site erythema		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Injection site erythema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site erythema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
General disorders and administrati on site conditions	Injection site erythema	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site reaction		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Injection site reaction	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site reaction	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site reaction	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Injection site urticaria		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site urticaria	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Injection site urticaria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site urticaria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
General disorders and administrati on site conditions	Medical device discomfort		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Medical device discomfort	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Medical device discomfort	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Medical device discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Vaccination site pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Vaccination site pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Vaccination site pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Vaccination site pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Fatigue		0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
General disorders and administration site conditions	Fatigue	Mild	0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Fatigue	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Fatigue	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Gait disturbance		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Gait disturbance	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Gait disturbance	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Gait disturbance	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site atrophy		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Injection site atrophy	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site atrophy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Injection site atrophy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site bruising		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Injection site bruising	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site bruising	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site bruising	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
General disorders and administrati on site conditions	Injection site haemorrhage		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site haemorrhage	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Injection site haemorrhage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site haemorrhage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Peripheral swelling		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
General disorders and administrati on site conditions	Peripheral swelling	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Peripheral swelling	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Peripheral swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Face oedema		0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
General disorders and administration site conditions	Face oedema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Face oedema	Moderate	0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Face oedema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Influenza like illness		0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
General disorders and administration site conditions	Influenza like illness	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
General disorders and administration site conditions	Influenza like illness	Moderate	0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
General disorders and administration site conditions	Influenza like illness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders			14.3% (4.7, 36.1)	27.3% (9.0, 58.6)	P=0.316, I <sup>2</sup> =0%	P=0.090, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Gastrointestinal disorders		Mild	14.3% (4.7, 36.1)	27.3% (9.0, 58.6)	P=0.316, I <sup>2</sup> =0%	P=0.090, I <sup>2</sup> =0%	0.471 (0.087, 2.545)	0.526 (0.129, 2.145) 0.371	-0.134 (-0.452, 0.183)	P=0.248, I <sup>2</sup> =2505%	P=0.317, I <sup>2</sup> =14%	P=0.120, I <sup>2</sup> =5865%	
Gastrointestinal disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Diarrhoea		4.8% (0.7, 27.1)	9.1% (1.3, 43.9)	P=0.574, I <sup>2</sup> =0%	P=0.010, I <sup>2</sup> =0%							
Gastrointestinal disorders	Diarrhoea	Mild	4.8% (0.7, 27.1)	9.1% (1.3, 43.9)	P=0.574, I <sup>2</sup> =0%	P=0.010, I <sup>2</sup> =0%	0.476 (0.039, 5.776)	0.476 (0.041, 5.495) 0.552	-0.055 (-0.264, 0.155)	P=0.193, I <sup>2</sup> =4110%	P=0.266, I <sup>2</sup> =1927%	P=0.055, I <sup>2</sup> =7288%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Gastrointestinal disorders	Diarrhoea	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Diarrhoea	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Vomiting		4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Vomiting	Mild	4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Gastrointestinal disorders	Vomiting	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Vomiting	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Nausea		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Nausea	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Nausea	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Gastrointestinal disorders	Nausea	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal pain upper		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal pain upper	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal pain upper	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Gastrointesti nal disorders	Abdominal pain upper	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Abdominal pain		0%	9.1% (1.3, 43.9)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Abdominal pain	Mild	0%	9.1% (1.3, 43.9)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Gastrointesti nal disorders	Abdominal pain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Abdominal pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Gastrointestinal disorders	Dyspepsia		4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Dyspepsia	Mild	4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Dyspepsia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Dyspepsia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapegsomatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapegsomatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Gastrointestinal disorders	Constipation		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Constipation	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Constipation	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Constipation	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Toothache		0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Gastrointesti nal disorders	Toothache	Mild	0%	9.1% (1.3, 43.9)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
Gastrointesti nal disorders	Toothache	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Toothache	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Abdominal discomfort		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Gastrointestinal disorders	Abdominal discomfort	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal discomfort	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal discomfort	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Enteritis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Enteritis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Gastrointestinal disorders	Enteritis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Enteritis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastrointestinal disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastrointestinal disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Gastrointestinal disorders	Gastrointestinal disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastrointestinal disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Aphthous ulcer		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Aphthous ulcer	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Aphthous ulcer	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Gastrointesti nal disorders	Aphthous ulcer	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastric disorder		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastric disorder	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastric disorder	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastric disorder	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Gastrointesti nal disorders	Lip swelling		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Lip swelling	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Lip swelling	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Lip swelling	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Gastrointestinal disorders	Abdominal distension		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal distension	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal distension	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal distension	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Noninfective gingivitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Gastrointestinal disorders	Noninfective gingivitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Noninfective gingivitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Noninfective gingivitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Gastrointestinal motility disorder		4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Gastrointesti nal disorders	Gastrointesti nal motility disorder	Mild	4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
Gastrointesti nal disorders	Gastrointesti nal motility disorder	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastrointesti nal motility disorder	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Nervous system disorders			0%	18.2% (4.6, 50.7)	P=1.000 , I <sup>2</sup> =0%	P=0.047 , I <sup>2</sup> =0%							
Nervous system disorders		Mild	0%	9.1% (1.3, 43.9)	P=1.000 , I <sup>2</sup> =0%	P=0.010 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.104 (-0.284 - 0.075)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Nervous system disorders		Moderate	0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Nervous system disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Headache		0%	18.2% (4.6, 50.7)	P=1.000, I <sup>2</sup> =0%	P=0.047, I <sup>2</sup> =0%							
Nervous system disorders	Headache	Mild	0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.010, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.104 (-0.284 - 0.075)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Nervous system disorders	Headache	Moderate	0%	9.1% (1.3, 43.9)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Nervous system disorders	Headache	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Nervous system disorders	Dizziness		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Nervous system disorders	Dizziness	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Nervous system disorders	Dizziness	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Dizziness	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Post-traumatic headache		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Post-traumatic headache	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Post-traumatic headache	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Nervous system disorders	Post-traumatic headache	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Migraine		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Migraine	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Migraine	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Nervous system disorders	Migraine	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Nervous system disorders	Tremor		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Nervous system disorders	Tremor	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Nervous system disorders	Tremor	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Nervous system disorders	Tremor	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications			4.8% (0.7, 27.1)	27.3% (9.0, 58.6)	P=0.574, I <sup>2</sup> =0%	P=0.412, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications		Mild	4.8% (0.7, 27.1)	27.3% (9.0, 58.6)	P=0.574, I <sup>2</sup> =0%	P=0.412, I <sup>2</sup> =0%	0.137 (0.012, 1.556)	0.185 (0.022, 1.554) 0.12	-0.219 (-0.497, 0.059)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Head injury		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Head injury	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Head injury	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Head injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Arthropod bite		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Arthropod bite	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Arthropod bite	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Arthropod bite	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Post-traumatic pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Post-traumatic pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Post-traumatic pain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Post-traumatic pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Contusion		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Contusion	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Contusion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Contusion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ligament sprain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ligament sprain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Ligament sprain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ligament sprain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Skin laceration		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Skin laceration	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Skin laceration	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Skin laceration	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Animal bite		0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal bite	Mild	0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Animal bite	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Animal bite	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ankle fracture		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Ankle fracture	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ankle fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ankle fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Burns second degree		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns second degree	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns second degree	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Burns second degree	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Face injury		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Face injury	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Face injury	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Face injury	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Fall		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Fall	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Fall	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Fall	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Laceration		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Laceration	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Laceration	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Laceration	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Meniscus injury		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Meniscus injury	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Meniscus injury	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Meniscus injury	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Muscle strain		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Muscle strain	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Muscle strain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Muscle strain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Thermal burn		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Thermal burn	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Thermal burn	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Thermal burn	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Wrist fracture		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Wrist fracture	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Wrist fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Wrist fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Radius fracture		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Radius fracture	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Radius fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Radius fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal scratch		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Animal scratch	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal scratch	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Animal scratch	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Eye injury		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Eye injury	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Eye injury	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Eye injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Joint injury		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Joint injury	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Joint injury	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Joint injury	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Burns first degree		0%	9.1% (1.3, 43.9)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns first degree	Mild	0%	9.1% (1.3, 43.9)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Burns first degree	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Burns first degree	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Concussion		0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Concussion	Mild	0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Concussion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Concussion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Upper limb fracture		4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Upper limb fracture	Mild	4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Upper limb fracture	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Injury, poisoning and procedural complications	Upper limb fracture	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders			4.8% (0.7, 27.1)	9.1% (1.3, 43.9)	P=0.574 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders		Mild	4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Skin and subcutaneous tissue disorders		Moderate	0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Skin and subcutaneous tissue disorders	Rash	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis allergic		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Skin and subcutaneous tissue disorders	Dermatitis allergic	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis allergic	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria		0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Skin and subcutaneous tissue disorders	Urticaria	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria	Moderate	0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Urticaria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Skin and subcutaneous tissue disorders	Eczema		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Eczema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Eczema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Eczema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Skin and subcutaneous tissue disorders	Dermatitis contact		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis contact	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis contact	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Skin and subcutaneous tissue disorders	Dermatitis contact	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria papular		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria papular	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria papular	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Skin and subcutaneous tissue disorders	Urticaria papular	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Cafe au lait spots		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Cafe au lait spots	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Skin and subcutaneous tissue disorders	Cafe au lait spots	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Cafe au lait spots	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Keratosis pilaris		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Keratosis pilaris	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Skin and subcutaneous tissue disorders	Keratosis pilaris	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Keratosis pilaris	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Pityriasis alba		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Skin and subcutaneous tissue disorders	Pityriasis alba	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Pityriasis alba	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Pityriasis alba	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash erythematous		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Skin and subcutaneous tissue disorders	Rash erythematous	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash erythematous	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash erythematous	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Skin and subcutaneous tissue disorders	Rash pruritic		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash pruritic	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash pruritic	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash pruritic	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Skin and subcutaneous tissue disorders	Dermatitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Skin and subcutaneous tissue disorders	Dermatitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dyshidrotic eczema		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria chronic		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria chronic	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Skin and subcutaneous tissue disorders	Urticaria chronic	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria chronic	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Petechiae		4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Petechiae	Mild	4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Skin and subcutaneous tissue disorders	Petechiae	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Petechiae	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders			4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Musculoskeletal and connective tissue disorders		Mild	4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Musculoskel etal and connective tissue disorders	Pain in extremity		4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Pain in extremity	Mild	4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Musculoskel etal and connective tissue disorders	Pain in extremity	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Musculoskeletal and connective tissue disorders	Pain in extremity	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthralgia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Musculoskeletal and connective tissue disorders	Arthralgia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthralgia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthralgia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Musculoskeletal and connective tissue disorders	Musculoskeletal pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Musculoskeletal and connective tissue disorders	Neck pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthritis reactive		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Musculoskeletal and connective tissue disorders	Arthritis reactive	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthritis reactive	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Musculoskeletal and connective tissue disorders	Arthritis reactive	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Back pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Back pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Musculoskeletal and connective tissue disorders	Back pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Back pain	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck mass		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Musculoskeletal and connective tissue disorders	Neck mass	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck mass	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck mass	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Musculoskeletal and connective tissue disorders	Pain in jaw		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Pain in jaw	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Pain in jaw	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Musculoskeletal and connective tissue disorders	Pain in jaw	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Synovial cyst		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Musculoskeletal and connective tissue disorders	Synovial cyst	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Synovial cyst	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Synovial cyst	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Musculoskeletal and connective tissue disorders	Scoliosis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Scoliosis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Scoliosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Musculoskeletal and connective tissue disorders	Scoliosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders			4.8% (0.7, 27.1)	0%	P=0.040, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders		Mild	4.8% (0.7, 27.1)	0%	P=0.040, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA)	0.035 (-0.044 - 0.114)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Metabolism and nutrition disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypertriglyceridaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypertriglyceridaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Metabolism and nutrition disorders	Hypertriglyceridaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypertriglyceridaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypercholesterolaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Metabolism and nutrition disorders	Hypercholesterolaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypercholesterolaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypercholesterolaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Decreased appetite		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Metabolism and nutrition disorders	Decreased appetite	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Decreased appetite	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Decreased appetite	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Metabolism and nutrition disorders	Hyperuricemia		4.8% (0.7, 27.1)	0%	P=0.040, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperuricemia	Mild	4.8% (0.7, 27.1)	0%	P=0.040, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.035 (-0.044 - 0.114)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Hyperuricemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperuricemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Metabolism and nutrition disorders	Polydipsia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Polydipsia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Polydipsia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Metabolism and nutrition disorders	Polydipsia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Calcium deficiency		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Calcium deficiency	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Calcium deficiency	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Metabolism and nutrition disorders	Calcium deficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperglycaemia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperglycaemia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Metabolism and nutrition disorders	Hyperglycae mia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperglycae mia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperlipidae mia		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperlipidae mia	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Metabolism and nutrition disorders	Hyperlipidaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperlipidaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders			9.5% (2.4, 31.1)	9.1% (1.3, 43.9)	P=0.197, I <sup>2</sup> =44.1%	P=0.010, I <sup>2</sup> =0%							
Eye disorders		Mild	9.5% (2.4, 31.1)	9.1% (1.3, 43.9)	P=0.197, I <sup>2</sup> =44.1%	P=0.010, I <sup>2</sup> =0%	0.714 (0.038, 13.574)	0.810 (0.144, 4.564) 0.811	-0.020 (-0.202, 0.162)	P=0.391, I <sup>2</sup> =0%	P=0.428, I <sup>2</sup> =0%	P=0.274, I <sup>2</sup> =1629%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Eye disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Refraction disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Refraction disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Eye disorders	Refraction disorder	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Refraction disorder	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Conjunctivit is allergic		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Conjunctivit is allergic	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Conjunctivit is allergic	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Eye disorders	Conjunctivitis allergic	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye swelling		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye swelling	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye swelling	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye swelling	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Eye disorders	Strabismus		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Strabismus	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Strabismus	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Strabismus	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Eye disorders	Myopia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Myopia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Myopia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Myopia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye haemorrhage		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Eye disorders	Eye haemorrhage	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye haemorrhage	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye haemorrhage	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Astigmatism		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Astigmatism	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Eye disorders	Astigmatism	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Astigmatism	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Corneal epithelium defect		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Corneal epithelium defect	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Eye disorders	Corneal epithelium defect	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Corneal epithelium defect	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Eye pain		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Eye pain	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Eye pain	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Eye disorders	Eye pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Xerophthal mia		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Xerophthal mia	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Xerophthal mia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Xerophthal mia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Eye disorders	Vernal keratoconjunctivitis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Vernal keratoconjunctivitis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Vernal keratoconjunctivitis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Vernal keratoconjunctivitis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Eye disorders	Vitreous opacities		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Vitreous opacities	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Vitreous opacities	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Vitreous opacities	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Hypermetro pia		4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Eye disorders	Hypermetropia	Mild	4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Hypermetropia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Hypermetropia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Papilloedema		4.8% (0.7, 27.1)	9.1% (1.3, 43.9)	P=0.040, I <sup>2</sup> =0%	P=0.010, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Eye disorders	Papilloedema	Mild	4.8% (0.7, 27.1)	9.1% (1.3, 43.9)	P=0.040, I <sup>2</sup> =0%	P=0.010, I <sup>2</sup> =0%	NA (NA, NA)	0.333 (0.067, 1.652) 0.178	-0.070 (-0.217, 0.078)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Papilloedema	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Papilloedema	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders			14.3% (4.7, 36.1)	18.2% (4.6, 50.7)	P=0.357, I <sup>2</sup> =0%	P=0.047, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Blood and lymphatic system disorders		Mild	9.5% (2.4, 31.1)	18.2% (4.6, 50.7)	P=0.197 , I <sup>2</sup> =44.1 %	P=0.047 , I <sup>2</sup> =0%	0.290 (0.024, 3.568)	0.436 (0.090, 2.113) 0.303	-0.109 (-0.346 - 0.127)	P=0.652, I <sup>2</sup> =0%	P=0.800, I <sup>2</sup> =0%	P=0.366, I <sup>2</sup> =0%	
Blood and lymphatic system disorders		Moderate	4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphaden opathy		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Blood and lymphatic system disorders	Lymphadenopathy	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenopathy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenopathy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Blood and lymphatic system disorders	Anaemia		0%	18.2% (4.6, 50.7)	P=1.000, I <sup>2</sup> =0%	P=0.047, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Anaemia	Mild	0%	18.2% (4.6, 50.7)	P=1.000, I <sup>2</sup> =0%	P=0.047, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.194 (-0.426 - 0.038)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.145, I <sup>2</sup> =528 1%	
Blood and lymphatic system disorders	Anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Blood and lymphatic system disorders	Neutropenia		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Neutropenia	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Neutropenia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Blood and lymphatic system disorders	Neutropenia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Granulocytopenia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Granulocytopenia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Granulocytopenia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Blood and lymphatic system disorders	Granulocytopenia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenitis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenitis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Blood and lymphatic system disorders	Lymphadenitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Iron deficiency anaemia		9.5% (2.4, 31.1)	0%	P=0.420, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Iron deficiency anaemia	Mild	4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Blood and lymphatic system disorders	Iron deficiency anaemia	Moderate	4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Iron deficiency anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Thymus disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Blood and lymphatic system disorders	Thymus disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Thymus disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Thymus disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Hypochromic anaemia		4.8% (0.7, 27.1)	0%	P=0.040, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Blood and lymphatic system disorders	Hypochromic anaemia	Mild	4.8% (0.7, 27.1)	0%	P=0.040, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.035 (-0.044 - 0.114)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Hypochromic anaemia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Hypochromic anaemia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Immune system disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Seasonal allergy		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Immune system disorders	Seasonal allergy	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Seasonal allergy	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Seasonal allergy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Hypersensitivity		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Hypersensitivity	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Immune system disorders	Hypersensitivity	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Hypersensitivity	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Allergy to animal		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Allergy to animal	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Immune system disorders	Allergy to animal	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Immune system disorders	Allergy to animal	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Immune system disorders	Food allergy		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Immune system disorders	Food allergy	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Immune system disorders	Food allergy	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Immune system disorders	Food allergy	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders			28.6% (13.4, 50.8)	27.3% (9.0, 58.6)	P=0.137, I <sup>2</sup> =0%	P=0.412, I <sup>2</sup> =0%							
Endocrine disorders		Mild	28.6% (13.4, 50.8)	27.3% (9.0, 58.6)	P=0.137, I <sup>2</sup> =0%	P=0.412, I <sup>2</sup> =0%	1.167 (0.220, 6.199)	1.111 (0.352, 3.510) 0.858	0.030 (-0.290, 0.350)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Endocrine disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Secondary hypothyroidism		23.8% (10.3, 46.0)	0%	P=0.182, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Secondary hypothyroidism	Mild	23.8% (10.3, 46.0)	0%	P=0.182, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.249 (0.064 - 0.434)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Secondary hypothyroidism	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Secondary hypothyroidism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Endocrine disorders	Hypothyroidism		0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Endocrine disorders	Hypothyroidism	Mild	0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	-0.090 (-0.259 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Hypothyroidism	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Hypothyroidism	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Endocrine disorders	Adrenal insufficiency		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Endocrine disorders	Adrenal insufficiency	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Endocrine disorders	Adrenal insufficiency	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Endocrine disorders	Adrenal insufficiency	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Endocrine disorders	Precocious puberty		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Endocrine disorders	Precocious puberty	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Precocious puberty	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Precocious puberty	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Diabetes insipidus		4.8% (0.7, 27.1)	9.1% (1.3, 43.9)	P=0.574, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Endocrine disorders	Diabetes insipidus	Mild	4.8% (0.7, 27.1)	9.1% (1.3, 43.9)	P=0.574 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%	0.529 (0.030, 9.499)	0.556 (0.039, 7.957) 0.665	-0.040 (-0.232 - 0.153)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
Endocrine disorders	Diabetes insipidus	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Endocrine disorders	Diabetes insipidus	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Endocrine disorders	Secondary adrenocortical insufficiency		4.8% (0.7, 27.1)	9.1% (1.3, 43.9)	P=0.574 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Endocrine disorders	Secondary adrenocortical insufficiency	Mild	4.8% (0.7, 27.1)	9.1% (1.3, 43.9)	P=0.574, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	0.529 (0.030, 9.499)	0.556 (0.039, 7.957) 0.665	-0.040 (-0.232, 0.153)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Secondary adrenocortical insufficiency	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Secondary adrenocortical insufficiency	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Reproductive system and breast disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Penile adhesion		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Reproductive system and breast disorders	Penile adhesion	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Penile adhesion	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Penile adhesion	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Reproductive system and breast disorders	Gynaecomastia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Gynaecomastia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Gynaecomastia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Gynaecomastia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Reproductiv e system and breast disorders	Genital discomfort		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Genital discomfort	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Genital discomfort	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Reproductiv e system and breast disorders	Genital discomfort	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Pelvic fluid collection		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Pelvic fluid collection	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Pelvic fluid collection	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Reproductiv e system and breast disorders	Pelvic fluid collection	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Testicular appendage torsion		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Testicular appendage torsion	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Reproductiv e system and breast disorders	Testicular appendage torsion	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Testicular appendage torsion	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Balanoposth itis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Reproductiv e system and breast disorders	Balanoposth itis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Reproductive system and breast disorders	Balanoposthitis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Balanoposthitis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Ear and labyrinth disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Ear pain		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Ear pain	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Ear pain	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Ear and labyrinth disorders	Ear pain	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Cerumen impaction		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Cerumen impaction	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Cerumen impaction	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Ear and labyrinth disorders	Cerumen impaction	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Motion sickness		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Motion sickness	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Motion sickness	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Ear and labyrinth disorders	Motion sickness	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Psychiatric disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Attention deficit/hyperactivity disorder		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Psychiatric disorders	Attention deficit/hyperactivity disorder	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Attention deficit/hyperactivity disorder	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Attention deficit/hyperactivity disorder	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Affect lability		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Psychiatric disorders	Affect lability	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Affect lability	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Affect lability	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Enuresis		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Enuresis	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Psychiatric disorders	Enuresis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Enuresis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Depressive symptom		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Depressive symptom	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Depressive symptom	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Psychiatric disorders	Depressive symptom	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders			0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders		Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders		Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Cardiac disorders	Sinoatrial block		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Sinoatrial block	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Sinoatrial block	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Sinoatrial block	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Sinus tachycardia		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Cardiac disorders	Sinus tachycardia	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Sinus tachycardia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Sinus tachycardia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Tachycardia		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Cardiac disorders	Tachycardia	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Tachycardia	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Tachycardia	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Myocarditis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Myocarditis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Cardiac disorders	Myocarditis	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Myocarditis	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Wandering pacemaker		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Wandering pacemaker	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Cardiac disorders	Wandering pacemaker	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Cardiac disorders	Wandering pacemaker	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Renal and urinary disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Pollakiuria		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Pollakiuria	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Pollakiuria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Pollakiuria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Renal and urinary disorders	Polyuria		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Polyuria	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Polyuria	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Polyuria	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Nocturia		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Renal and urinary disorders	Nocturia	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Nocturia	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Nocturia	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders			4.8% (0.7, 27.1)	0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Vascular disorders		Mild	4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Vascular disorders		Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Vascular disorders		Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Vascular disorders	Hypotension		4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Vascular disorders	Hypotension	Mild	4.8% (0.7, 27.1)	0%	P=0.574 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA, NA)	NA (NA, NA) NA	0.050 (-0.044 - 0.143)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Vascular disorders	Hypotension	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Vascular disorders	Hypotension	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Vascular disorders	Cyanosis		0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Vascular disorders	Cyanosis	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Vascular disorders	Cyanosis	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Cyanosis	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders			0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Congenital, familial and genetic disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Supernumerary teeth		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Congenital, familial and genetic disorders	Supernumerary teeth	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Supernumerary teeth	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Supernumerary teeth	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Buried penis syndrome		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interactio n
Multiple pituitary hormone deficiencies													
Congenital, familial and genetic disorders	Buried penis syndrome	Mild	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Buried penis syndrome	Moderate	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Buried penis syndrome	Severe	0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Hepatobiliar y disorders			0%	0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Hepatobiliary disorders		Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders		Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders		Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders	Hepatomegaly		0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.21.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p-value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies													
Hepatobiliary disorders	Hepatomegaly	Mild	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders	Hepatomegaly	Moderate	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders	Hepatomegaly	Severe	0%	0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.													

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Any adverse event			83.4% (75.1, 89.4)	79.6% (67.7, 87.9)	P=0.004 , I <sup>2</sup> =87.9 %	P=0.019 , I <sup>2</sup> =82%							P=0.491
Any adverse event		Mild	65.5% (56.5, 73.5)	54.6% (41.2, 67.4)	P=0.000 , I <sup>2</sup> =94.6 %	P=0.000 , I <sup>2</sup> =95%	1.504 (0.788 - 2.870)	1.117 (0.931 - 1.341)	0.073 (-0.044 - 0.189)	P=0.249, I <sup>2</sup> =246 %	P=0.029, I <sup>2</sup> =789 %	P=0.080, I <sup>2</sup> =673 %	P=0.291
Any adverse event		Moderate	18.9% (13.0, 26.6)	28.1% (18.0, 41.1)	P=0.011 , I <sup>2</sup> =84.7 %	P=0.003 , I <sup>2</sup> =88%	0.730 (0.356 - 1.497)	0.792 (0.467 - 1.343)	-0.045 (-0.149 - 0.060)	P=0.261, I <sup>2</sup> =209 %	P=0.302, I <sup>2</sup> =602 %	P=0.080, I <sup>2</sup> =673 %	P=0.871

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Any adverse event		Severe	1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.729, I <sup>2</sup> =0%	P=0.788
Infections and infestations			58.4% (50.3, 66.1)	58.2% (47.1, 68.5)	P=0.247, I <sup>2</sup> =25.4%	P=0.690, I <sup>2</sup> =0%							P=0.113
Infections and infestations		Mild	47.1% (38.9, 55.4)	43.4% (32.7, 54.8)	P=0.005, I <sup>2</sup> =87.6%	P=0.037, I <sup>2</sup> =77%	1.180 (0.669 - 2.079)	1.090 (0.809 - 1.468)	0.039 (-0.093 - 0.170)	P=0.983, I <sup>2</sup> =0%	P=0.887, I <sup>2</sup> =0%	P=0.996, I <sup>2</sup> =0%	P=0.151
Infections and infestations		Moderate	13.3% (8.1, 20.9)	18.5% (10.7, 30.0)	P=0.012, I <sup>2</sup> =84.2%	P=0.030, I <sup>2</sup> =79%	0.617 (0.266 - 1.434)	0.674 (0.340 - 1.336)	-0.050 (-0.140 - 0.041)	P=0.856, I <sup>2</sup> =0%	P=0.796, I <sup>2</sup> =0%	P=0.500, I <sup>2</sup> =0%	P=0.545

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations		Severe	1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.729, I <sup>2</sup> =0%	P=0.788
Infections and infestations	Upper respiratory tract infection		36.9% (27.3, 47.6)	36.9% (25.4, 50.1)	P=0.000, I <sup>2</sup> =95.1%	P=0.000, I <sup>2</sup> =93%							P=0.599
Infections and infestations	Upper respiratory tract infection	Mild	36.9% (27.3, 47.6)	34.1% (22.8, 47.6)	P=0.000, I <sup>2</sup> =95.1%	P=0.000, I <sup>2</sup> =92%	0.782 (0.381 - 1.608)	0.867 (0.574 - 1.309)	-0.035 (-0.140 - 0.069)	P=0.336, I <sup>2</sup> =0%	P=0.282, I <sup>2</sup> =1372%	P=0.775, I <sup>2</sup> =0%	P=0.609
Infections and infestations	Upper respiratory tract infection	Moderate	0.7% (0.1, 4.6)	4.1% (1.3, 11.9)	P=0.973, I <sup>2</sup> =0%	P=0.522, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.038 (-0.080 - 0.004)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.578, I <sup>2</sup> =0%	P=0.875

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Upper respiratory tract infection	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Nasopharyngitis		10.6% (6.0, 18.3)	9.5% (4.6, 18.7)	P=0.026, I <sup>2</sup> =79.7%	P=0.292, I <sup>2</sup> =10%							P=0.221
Infections and infestations	Nasopharyngitis	Mild	9.5% (5.2, 16.8)	7.9% (3.6, 16.5)	P=0.036, I <sup>2</sup> =77.3%	P=0.458, I <sup>2</sup> =0%	0.889 (0.308 - 2.567)	0.898 (0.342 - 2.357)	-0.008 (-0.078 - 0.063)	P=0.259, I <sup>2</sup> =2163%	P=0.257, I <sup>2</sup> =2217%	P=0.353, I <sup>2</sup> =0%	P=0.328
Infections and infestations	Nasopharyngitis	Moderate	1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	0.533 (0.032 - 8.755)	0.539 (0.035 - 8.402)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.690

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Nasopharyngitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Pharyngitis		8.9% (4.6, 16.6)	14.8% (8.1, 25.5)	P=0.054, I <sup>2</sup> =73%	P=0.075, I <sup>2</sup> =69%							P=0.680
Infections and infestations	Pharyngitis	Mild	7.7% (3.8, 15.0)	14.8% (8.1, 25.5)	P=0.070, I <sup>2</sup> =69.6%	P=0.075, I <sup>2</sup> =69%	0.328 (0.116 - 0.929)	0.377 (0.153 - 0.932)	-0.079 (-0.158 - 0.001)	P=0.387, I <sup>2</sup> =0%	P=0.349, I <sup>2</sup> =0%	P=0.525, I <sup>2</sup> =0%	P=0.582
Infections and infestations	Pharyngitis	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Pharyngitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Respiratory tract infection		6.1% (3.2, 11.4)	5.6% (2.1, 14.1)	P=0.811, I <sup>2</sup> =0%	P=0.363, I <sup>2</sup> =0%							P=0.577
Infections and infestations	Respiratory tract infection	Mild	4.8% (2.3, 9.8)	4.0% (1.3, 11.6)	P=0.633, I <sup>2</sup> =0%	P=0.607, I <sup>2</sup> =0%	1.266 (0.319 - 5.030)	1.254 (0.333 - 4.725)	0.010 (-0.045 - 0.064)	P=0.489, I <sup>2</sup> =0%	P=0.490, I <sup>2</sup> =0%	P=0.474, I <sup>2</sup> =0%	P=0.579
Infections and infestations	Respiratory tract infection	Moderate	2.0% (0.6, 6.7)	2.0% (0.4, 9.2)	P=0.395, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	1.081 (0.095 - 12.293)	1.079 (0.101 - 11.544)	0.001 (-0.030 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.765
Infections and infestations	Respiratory tract infection	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

						Lonapegsomatropin vs. Daily somatropin							
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Bronchitis		7.3% (3.8, 13.5)	5.1% (1.9, 12.7)	P=0.088, I <sup>2</sup> =65.6%	P=0.938, I <sup>2</sup> =0%							P=0.955
Infections and infestations	Bronchitis	Mild	6.4% (3.1, 12.9)	3.9% (1.1, 12.6)	P=0.077, I <sup>2</sup> =68.1%	P=0.339, I <sup>2</sup> =0%	1.955 (0.388 - 9.860)	1.875 (0.407 - 8.642)	0.022 (-0.026 - 0.070)	P=0.826, I <sup>2</sup> =0%	P=0.831, I <sup>2</sup> =0%	P=0.506, I <sup>2</sup> =0%	P=0.996
Infections and infestations	Bronchitis	Moderate	1.4% (0.3, 5.3)	3.7% (1.1, 12.1)	P=0.961, I <sup>2</sup> =0%	P=0.390, I <sup>2</sup> =0%	0.532 (0.074 - 3.841)	0.538 (0.077 - 3.757)	-0.012 (-0.051 - 0.028)	P=0.371, I <sup>2</sup> =0%	P=0.374, I <sup>2</sup> =0%	P=0.299, I <sup>2</sup> =724%	P=0.693
Infections and infestations	Bronchitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Tonsillitis		4.4% (1.8, 10.6)	4.1% (1.3, 11.9)	P=0.143 , I <sup>2</sup> =53.4 %	P=0.522 , I <sup>2</sup> =0%							P=0.958
Infections and infestations	Tonsillitis	Mild	4.4% (1.8, 10.6)	3.9% (1.1, 12.6)	P=0.143 , I <sup>2</sup> =53.4 %	P=0.339 , I <sup>2</sup> =0%	1.075 (0.188 - 6.153)	1.070 (0.205 - 5.579)	0.002 (-0.041 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.768
Infections and infestations	Tonsillitis	Moderate	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.733
Infections and infestations	Tonsillitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Gastroenteritis		3.0% (1.1, 7.8)	5.7% (2.0, 15.1)	P=0.365, I <sup>2</sup> =0%	P=0.243, I <sup>2</sup> =27%							P=0.377
Infections and infestations	Gastroenteritis	Mild	3.0% (1.1, 7.8)	3.7% (1.1, 12.1)	P=0.365, I <sup>2</sup> =0%	P=0.390, I <sup>2</sup> =0%	1.081 (0.191 - 6.101)	1.078 (0.204 - 5.701)	0.002 (-0.041 - 0.045)	P=0.683, I <sup>2</sup> =0%	P=0.683, I <sup>2</sup> =0%	P=0.710, I <sup>2</sup> =0%	P=0.268
Infections and infestations	Gastroenteritis	Moderate	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.733
Infections and infestations	Gastroenteritis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Rhinitis		3.4% (1.4, 8.0)	4.0% (1.3, 11.6)	P=0.707, I <sup>2</sup> =0%	P=0.607, I <sup>2</sup> =0%							P=0.919

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Rhinitis	Mild	3.4% (1.4, 8.0)	4.0% (1.3, 11.6)	P=0.707, I <sup>2</sup> =0%	P=0.607, I <sup>2</sup> =0%	0.893 (0.207 - 3.842)	0.896 (0.220 - 3.649)	-0.004 (-0.055 - 0.047)	P=0.851, I <sup>2</sup> =0%	P=0.852, I <sup>2</sup> =0%	P=0.824, I <sup>2</sup> =0%	P=0.919
Infections and infestations	Rhinitis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Rhinitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Pharyngitis streptococcal		3.1% (1.1, 8.4)	1.2% (0.2, 8.2)	P=0.249, I <sup>2</sup> =24.7%	P=0.970, I <sup>2</sup> =0%							P=0.109

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Pharyngitis streptococcal	Mild	2.0% (0.6, 6.7)	1.2% (0.2, 8.2)	P=0.395, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.233
Infections and infestations	Pharyngitis streptococcal	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.331
Infections and infestations	Pharyngitis streptococcal	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Pneumonia		2.2% (0.7, 6.6)	4.0% (1.3, 11.6)	P=0.530, I <sup>2</sup> =0%	P=0.607, I <sup>2</sup> =0%							P=0.657

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Pneumonia	Mild	2.1% (0.6, 7.0)	2.0% (0.4, 9.4)	P=0.349, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	1.072 (0.094 - 12.224)	1.070 (0.100 - 11.427)	0.001 (-0.030 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.467
Infections and infestations	Pneumonia	Moderate	1.1% (0.2, 5.1)	3.7% (1.1, 12.1)	P=0.711, I <sup>2</sup> =0%	P=0.390, I <sup>2</sup> =0%	0.260 (0.023 - 2.958)	0.270 (0.025 - 2.886)	-0.018 (-0.055 - 0.018)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.776
Infections and infestations	Pneumonia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Sinusitis		1.1% (0.2, 5.1)	2.5% (0.6, 9.6)	P=0.711, I <sup>2</sup> =0%	P=0.957, I <sup>2</sup> =0%							P=0.372
Infections and infestations	Sinusitis	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.505

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Sinusitis	Moderate	1.1% (0.2, 5.1)	2.0% (0.4, 9.4)	P=0.711, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	0.538 (0.034 - 8.575)	0.538 (0.034 - 8.554)	-0.006 (-0.034 - 0.022)	P=0.335, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	P=0.324, I <sup>2</sup> =0%	P=0.704
Infections and infestations	Sinusitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Viral infection		6.5% (3.0, 13.4)	1.2% (0.2, 8.2)	P=0.091, I <sup>2</sup> =65.1%	P=0.970, I <sup>2</sup> =0%							P=0.354
Infections and infestations	Viral infection	Mild	5.3% (2.3, 11.8)	1.2% (0.2, 8.2)	P=0.122, I <sup>2</sup> =58.2%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.034 (0.005 - 0.063)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.389



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Viral infection	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Infections and infestations	Viral infection	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Ear infection		4.2% (1.7, 10.1)	2.0% (0.4, 9.2)	P=0.170, I <sup>2</sup> =47%	P=0.708, I <sup>2</sup> =0%							P=0.794
Infections and infestations	Ear infection	Mild	1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	0.533 (0.032 - 8.755)	0.539 (0.035 - 8.402)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.994

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Ear infection	Moderate	3.1% (1.1, 8.4)	1.2% (0.2, 8.2)	P=0.249, I <sup>2</sup> =24.7%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.020 (-0.002 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.729
Infections and infestations	Ear infection	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Respiratory tract infection viral		2.0% (0.6, 6.7)	2.0% (0.4, 9.2)	P=0.395, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.725
Infections and infestations	Respiratory tract infection viral	Mild	1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	0.533 (0.032 - 8.755)	0.539 (0.035 - 8.402)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.983

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Respiratory tract infection viral	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Infections and infestations	Respiratory tract infection viral	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Gastroenteritis viral		3.1% (1.1, 8.4)	2.0% (0.4, 9.4)	P=0.249, I <sup>2</sup> =24.7%	P=0.644, I <sup>2</sup> =0%							P=0.752
Infections and infestations	Gastroenteritis viral	Mild	3.1% (1.1, 8.4)	2.0% (0.4, 9.4)	P=0.249, I <sup>2</sup> =24.7%	P=0.644, I <sup>2</sup> =0%	1.614 (0.169 - 15.423)	1.614 (0.169 - 15.457)	0.008 (-0.026 - 0.042)	P=0.141, I <sup>2</sup> =5392%	P=0.142, I <sup>2</sup> =5362%	P=0.132, I <sup>2</sup> =5588%	P=0.752

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Gastroenteritis viral	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Gastroenteritis viral	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Otitis media acute		1.4% (0.3, 5.3)	2.0% (0.4, 9.2)	P=0.961, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.484
Infections and infestations	Otitis media acute	Mild	1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.729, I <sup>2</sup> =0%	P=0.293
Infections and infestations	Otitis media acute	Moderate	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.733

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Otitis media acute	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Conjunctivitis		1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.488
Infections and infestations	Conjunctivitis	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.688
Infections and infestations	Conjunctivitis	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Conjunctivitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Varicella		1.1% (0.2, 5.2)	2.0% (0.4, 9.4)	P=0.653, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.546
Infections and infestations	Varicella	Mild	1.1% (0.2, 5.2)	2.0% (0.4, 9.4)	P=0.653, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	0.529 (0.032 - 8.695)	0.535 (0.034 - 8.319)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.700
Infections and infestations	Varicella	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Infections and infestations	Varicella	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Enteritis infectious		1.1% (0.2, 5.1)	3.7% (1.1, 12.1)	P=0.711, I <sup>2</sup> =0%	P=0.390, I <sup>2</sup> =0%							P=0.776
Infections and infestations	Enteritis infectious	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.00, I <sup>2</sup> =0%	P=1.00, I <sup>2</sup> =0%	P=1.00, I <sup>2</sup> =0%	P=0.718
Infections and infestations	Enteritis infectious	Moderate	0.7% (0.1, 4.6)	3.7% (1.1, 12.1)	P=0.973, I <sup>2</sup> =0%	P=0.390, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.025 (-0.060 - 0.009)	P=1.00, I <sup>2</sup> =0%	P=1.00, I <sup>2</sup> =0%	P=1.00, I <sup>2</sup> =0%	P=0.594
Infections and infestations	Enteritis infectious	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Influenza		1.4% (0.3, 5.3)	2.0% (0.4, 9.2)	P=0.961, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.783
Infections and infestations	Influenza	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.00, I <sup>2</sup> =0%	P=1.00, I <sup>2</sup> =0%	P=1.00, I <sup>2</sup> =0%	P=0.733
Infections and infestations	Influenza	Moderate	1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.729, I <sup>2</sup> =0%	P=0.536
Infections and infestations	Influenza	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Enterobiasis		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.679
Infections and infestations	Enterobiasis	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.679
Infections and infestations	Enterobiasis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Enterobiasis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Herpangina		3.2% (1.1, 8.8)	1.2% (0.2, 8.2)	P=0.214, I <sup>2</sup> =35.2%	P=0.970, I <sup>2</sup> =0%							P=0.493

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Herpangina	Mild	3.2% (1.1, 8.8)	1.2% (0.2, 8.2)	P=0.214 , I <sup>2</sup> =35.2%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.020 (-0.002 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.493
Infections and infestations	Herpangina	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Infections and infestations	Herpangina	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Infections and infestations	Otitis media		2.1% (0.6, 7.0)	2.0% (0.4, 9.4)	P=0.349 , I <sup>2</sup> =0%	P=0.644 , I <sup>2</sup> =0%							P=0.767

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Otitis media	Mild	2.1% (0.6, 7.0)	2.0% (0.4, 9.4)	P=0.349, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	1.072 (0.094 - 12.224)	1.070 (0.100 - 11.427)	0.001 (-0.030 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.767
Infections and infestations	Otitis media	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Otitis media	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Periodontitis		2.1% (0.6, 7.0)	1.2% (0.2, 8.2)	P=0.349, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.834
Infections and infestations	Periodontitis	Mild	2.1% (0.6, 7.0)	1.2% (0.2, 8.2)	P=0.349, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.834

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Periodontitis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Periodontitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Helminthic infection		1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.994
Infections and infestations	Helminthic infection	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Helminthic infection	Moderate	1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	0.533 (0.032 - 8.755)	0.539 (0.035 - 8.402)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.994

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Helminthic infection	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Pharyngoton sillitis		1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.994
Infections and infestations	Pharyngoton sillitis	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.733
Infections and infestations	Pharyngoton sillitis	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Pharyngotonsillitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Viral upper respiratory tract infection		1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.994
Infections and infestations	Viral upper respiratory tract infection	Mild	1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	0.533 (0.032 - 8.755)	0.539 (0.035 - 8.402)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.994
Infections and infestations	Viral upper respiratory tract infection	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Viral upper respiratory tract infection	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Hordeolum		1.1% (0.2, 5.2)	2.0% (0.4, 9.2)	P=0.653, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.991
Infections and infestations	Hordeolum	Mild	1.1% (0.2, 5.2)	2.0% (0.4, 9.2)	P=0.653, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	0.537 (0.033 - 8.607)	0.537 (0.033 - 8.628)	-0.006 (-0.034 - 0.022)	P=0.338, I <sup>2</sup> =0%	P=0.339, I <sup>2</sup> =0%	P=0.337, I <sup>2</sup> =0%	P=0.991
Infections and infestations	Hordeolum	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Hordeolum	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Pulpitis dental		1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.536
Infections and infestations	Pulpitis dental	Mild	1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.729, I <sup>2</sup> =0%	P=0.536
Infections and infestations	Pulpitis dental	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Pulpitis dental	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Urinary tract infection		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.991
Infections and infestations	Urinary tract infection	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732
Infections and infestations	Urinary tract infection	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.717
Infections and infestations	Urinary tract infection	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Laryngitis		1.1% (0.2, 5.2)	2.0% (0.4, 9.4)	P=0.653, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.996

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Laryngitis	Mild	1.1% (0.2, 5.2)	2.0% (0.4, 9.4)	P=0.653 , I <sup>2</sup> =0%	P=0.644 , I <sup>2</sup> =0%	0.529 (0.032 - 8.695)	0.535 (0.034 - 8.319)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.996
Infections and infestations	Laryngitis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Infections and infestations	Laryngitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Infections and infestations	Oral herpes		1.1% (0.2, 5.2)	2.0% (0.4, 9.4)	P=0.653 , I <sup>2</sup> =0%	P=0.644 , I <sup>2</sup> =0%							P=0.996

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Oral herpes	Mild	1.1% (0.2, 5.2)	2.0% (0.4, 9.4)	P=0.653, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	0.529 (0.032 - 8.695)	0.535 (0.034 - 8.319)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.996
Infections and infestations	Oral herpes	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Oral herpes	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Hand-foot-and-mouth disease		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.993
Infections and infestations	Hand-foot-and-mouth disease	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.993

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Hand-foot-and-mouth disease	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Hand-foot-and-mouth disease	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Appendicitis		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Infections and infestations	Appendicitis	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Appendicitis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Appendicitis	Severe	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Infections and infestations	Atypical pneumonia		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Infections and infestations	Atypical pneumonia	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Atypical pneumonia	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Atypical pneumonia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Conjunctivitis bacterial		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.733
Infections and infestations	Conjunctivitis bacterial	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.733
Infections and infestations	Conjunctivitis bacterial	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Conjunctivitis bacterial	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Croup infectious		0.7% (0.1, 3.2)	2.1% (0.6, 7.1)	P=0.999 , I <sup>2</sup> =0%	P=0.919 , I <sup>2</sup> =0%							P=0.639
Infections and infestations	Croup infectious	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Infections and infestations	Croup infectious	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Infections and infestations	Croup infectious	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Infections and infestations	Cystitis		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Cystitis	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Infections and infestations	Cystitis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Cystitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Eczema infected		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Eczema infected	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Infections and infestations	Eczema infected	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Eczema infected	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Infected bite		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Infections and infestations	Infected bite	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Infected bite	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Infected bite	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Laryngitis viral		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.733
Infections and infestations	Laryngitis viral	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.733

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Laryngitis viral	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Laryngitis viral	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Otitis externa		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Infections and infestations	Otitis externa	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Otitis externa	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Otitis externa	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Rotavirus infection		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Infections and infestations	Rotavirus infection	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Infections and infestations	Rotavirus infection	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Rotavirus infection	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Vulvitis		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Infections and infestations	Vulvitis	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Infections and infestations	Vulvitis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Vulvitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Molluscum contagiosum		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Infections and infestations	Molluscum contagiosum	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Infections and infestations	Molluscum contagiosum	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Molluscum contagiosum	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Tinea pedis		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Tinea pedis	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.732
Infections and infestations	Tinea pedis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Infections and infestations	Tinea pedis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Infections and infestations	Tooth abscess		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.732
Infections and infestations	Tooth abscess	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Tooth abscess	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Tooth abscess	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Abscess limb		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Infections and infestations	Abscess limb	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Infections and infestations	Abscess limb	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Abscess limb	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Bacterial infection		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.732
Infections and infestations	Bacterial infection	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732
Infections and infestations	Bacterial infection	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Bacterial infection	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Chronic sinusitis		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Infections and infestations	Chronic sinusitis	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Infections and infestations	Chronic sinusitis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Chronic sinusitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Chronic tonsillitis		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Infections and infestations	Chronic tonsillitis	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Infections and infestations	Chronic tonsillitis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Chronic tonsillitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Folliculitis		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Folliculitis	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Infections and infestations	Folliculitis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Folliculitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Herpes virus infection		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Herpes virus infection	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732
Infections and infestations	Herpes virus infection	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Herpes virus infection	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Infectious mononucleosis		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.732
Infections and infestations	Infectious mononucleosis	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Infectious mononucleosis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Infectious mononucleosis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Sinobronchitis		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.732
Infections and infestations	Sinobronchitis	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732
Infections and infestations	Sinobronchitis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Sinobronchitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Subcutaneous abscess		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Infections and infestations	Subcutaneous abscess	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Subcutaneous abscess	Moderate	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Subcutaneous abscess	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Tonsillitis bacterial		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Infections and infestations	Tonsillitis bacterial	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Tonsillitis bacterial	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Tonsillitis bacterial	Severe	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Tracheitis		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Infections and infestations	Tracheitis	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Infections and infestations	Tracheitis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Tracheitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Gastrointestinal bacterial infection		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Gastrointestinal bacterial infection	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Infections and infestations	Gastrointestinal bacterial infection	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Gastrointestinal bacterial infection	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Mumps		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Infections and infestations	Mumps	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Mumps	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Infections and infestations	Mumps	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Infections and infestations	Myringitis		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.732
Infections and infestations	Myringitis	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.732
Infections and infestations	Myringitis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Infections and infestations	Myringitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Peritonsillar abscess		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.717
Infections and infestations	Peritonsillar abscess	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Infections and infestations	Peritonsillar abscess	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.717
Infections and infestations	Peritonsillar abscess	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations			34.3% (25.8, 44.0)	41.6% (28.8, 55.6)	P=0.000, I <sup>2</sup> =95.8%	P=0.000, I <sup>2</sup> =94%							P=0.303
Investigations		Mild	34.3% (25.8, 44.0)	41.6% (28.8, 55.6)	P=0.000, I <sup>2</sup> =95.8%	P=0.000, I <sup>2</sup> =94%	0.749 (0.376 - 1.493)	0.857 (0.597 - 1.231)	-0.045 (-0.154 - 0.064)	P=0.563, I <sup>2</sup> =0%	P=0.697, I <sup>2</sup> =0%	P=0.254, I <sup>2</sup> =2301%	P=0.303
Investigations		Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Blood glucose increased		13.4% (7.6, 22.5)	29.7% (18.1, 44.8)	P=0.022, I <sup>2</sup> =80.9%	P=0.010, I <sup>2</sup> =85%							P=0.623
Investigations	Blood glucose increased	Mild	13.4% (7.6, 22.5)	29.7% (18.1, 44.8)	P=0.022, I <sup>2</sup> =80.9%	P=0.010, I <sup>2</sup> =85%	0.353 (0.139 - 0.892)	0.453 (0.225 - 0.912)	-0.090 (-0.177 - -0.004)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.623
Investigations	Blood glucose increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Blood glucose increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Insulin-like growth factor increased		23.4% (15.9, 33.0)	6.0% (2.1, 15.9)	P=0.000, I <sup>2</sup> =92.3%	P=0.204, I <sup>2</sup> =38%							P=0.973

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Insulin-like growth factor increased	Mild	23.4% (15.9, 33.0)	6.0% (2.1, 15.9)	P=0.000, I <sup>2</sup> =92.3%	P=0.204, I <sup>2</sup> =38%	5.409 (1.504 - 19.453)	4.105 (1.310 - 12.869)	0.118 (0.049 - 0.188)	P=0.652, I <sup>2</sup> =0%	P=0.758, I <sup>2</sup> =0%	P=0.000, I <sup>2</sup> =93.6%	P=0.973
Investigations	Insulin-like growth factor increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Insulin-like growth factor increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Low density lipoprotein increased		2.1% (0.6, 7.0)	3.9% (1.1, 12.6)	P=0.349, I <sup>2</sup> =0%	P=0.339, I <sup>2</sup> =0%							P=0.979
Investigations	Low density lipoprotein increased	Mild	2.1% (0.6, 7.0)	3.9% (1.1, 12.6)	P=0.349, I <sup>2</sup> =0%	P=0.339, I <sup>2</sup> =0%	0.522 (0.071 - 3.859)	0.535 (0.078 - 3.651)	-0.012 (-0.051 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.979
Investigations	Low density lipoprotein increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Low density lipoprotein increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Blood alkaline phosphatase increased		1.1% (0.2, 5.2)	6.0% (2.1, 15.9)	P=0.653, I <sup>2</sup> =0%	P=0.204, I <sup>2</sup> =38%							P=0.356
Investigations	Blood alkaline phosphatase increased	Mild	1.1% (0.2, 5.2)	6.0% (2.1, 15.9)	P=0.653, I <sup>2</sup> =0%	P=0.204, I <sup>2</sup> =38%	0.167 (0.017 - 1.661)	0.178 (0.019 - 1.657)	-0.031 (-0.075 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.356
Investigations	Blood alkaline phosphatase increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Blood alkaline phosphatase increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatotropin Mean (95%CI)	Daily somatotropin Mean (95%CI)	Lonapeg somatotropin	Daily somatotropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Eosinophil count increased		2.1% (0.6, 7.0)	2.0% (0.4, 9.4)	P=0.349, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.572
Investigations	Eosinophil count increased	Mild	2.1% (0.6, 7.0)	2.0% (0.4, 9.4)	P=0.349, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	1.072 (0.094 - 12.224)	1.070 (0.100 - 11.427)	0.001 (-0.030 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.572
Investigations	Eosinophil count increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Eosinophil count increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Alanine aminotransferase increased		3.2% (1.1, 8.8)	2.0% (0.4, 9.2)	P=0.214, I <sup>2</sup> =35.2%	P=0.708, I <sup>2</sup> =0%							P=0.461

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Alanine aminotransferase increased	Mild	3.2% (1.1, 8.8)	2.0% (0.4, 9.2)	P=0.214, I <sup>2</sup> =35.2%	P=0.708, I <sup>2</sup> =0%	1.610 (0.168 - 15.436)	1.610 (0.167 - 15.538)	0.008 (-0.026 - 0.042)	P=0.143, I <sup>2</sup> =535%	P=0.144, I <sup>2</sup> =531%	P=0.127, I <sup>2</sup> =569%	P=0.461
Investigations	Alanine aminotransferase increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Alanine aminotransferase increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Blood iron increased		2.1% (0.6, 7.0)	2.5% (0.6, 9.6)	P=0.349, I <sup>2</sup> =0%	P=0.957, I <sup>2</sup> =0%							P=0.645

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Blood iron increased	Mild	2.1% (0.6, 7.0)	2.5% (0.6, 9.6)	P=0.349, I <sup>2</sup> =0%	P=0.957, I <sup>2</sup> =0%	0.529 (0.073 - 3.850)	0.536 (0.077 - 3.737)	-0.012 (-0.051 - 0.028)	P=0.380, I <sup>2</sup> =0%	P=0.380, I <sup>2</sup> =0%	P=0.474, I <sup>2</sup> =0%	P=0.645
Investigations	Blood iron increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Blood iron increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Blood uric acid increased		3.2% (1.1, 8.8)	3.9% (1.1, 12.6)	P=0.214, I <sup>2</sup> =35.2%	P=0.339, I <sup>2</sup> =0%							P=0.831
Investigations	Blood uric acid increased	Mild	3.2% (1.1, 8.8)	3.9% (1.1, 12.6)	P=0.214, I <sup>2</sup> =35.2%	P=0.339, I <sup>2</sup> =0%	0.794 (0.127 - 4.971)	0.803 (0.140 - 4.598)	-0.005 (-0.046 - 0.036)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.831

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Blood uric acid increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Blood uric acid increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Blood phosphorus increased		3.2% (1.1, 8.8)	2.0% (0.4, 9.4)	P=0.214, I <sup>2</sup> =35.2%	P=0.644, I <sup>2</sup> =0%							P=0.913
Investigations	Blood phosphorus increased	Mild	3.2% (1.1, 8.8)	2.0% (0.4, 9.4)	P=0.214, I <sup>2</sup> =35.2%	P=0.644, I <sup>2</sup> =0%	1.632 (0.164 - 16.254)	1.606 (0.173 - 14.912)	0.008 (-0.026 - 0.041)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.913

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigation s	Blood phosphorus increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Investigation s	Blood phosphorus increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Investigation s	Cortisol decreased		3.2% (1.1, 8.8)	1.2% (0.2, 8.2)	P=0.214 , I <sup>2</sup> =35.2%	P=0.970 , I <sup>2</sup> =0%							P=0.266
Investigation s	Cortisol decreased	Mild	3.2% (1.1, 8.8)	1.2% (0.2, 8.2)	P=0.214 , I <sup>2</sup> =35.2%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.020 (-0.002 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.266
Investigation s	Cortisol decreased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Cortisol decreased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Aspartate aminotransferase increased		2.1% (0.6, 7.0)	2.0% (0.4, 9.2)	P=0.349, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.846
Investigations	Aspartate aminotransferase increased	Mild	2.1% (0.6, 7.0)	2.0% (0.4, 9.2)	P=0.349, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	1.073 (0.097 - 11.858)	1.073 (0.097 - 11.888)	0.001 (-0.030 - 0.032)	P=0.210, I <sup>2</sup> =3645%	P=0.211, I <sup>2</sup> =3597%	P=0.211, I <sup>2</sup> =3600%	P=0.846
Investigations	Aspartate aminotransferase increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Aspartate aminotransferase increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Blood triglycerides increased		2.1% (0.6, 7.0)	2.0% (0.4, 9.4)	P=0.349, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.767
Investigations	Blood triglycerides increased	Mild	2.1% (0.6, 7.0)	2.0% (0.4, 9.4)	P=0.349, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	1.072 (0.094 - 12.224)	1.070 (0.100 - 11.427)	0.001 (-0.030 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.767
Investigations	Blood triglycerides increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Blood triglycerides increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Blood glucose abnormal		0.7% (0.1, 4.6)	3.9% (1.1, 12.6)	P=0.973, I <sup>2</sup> =0%	P=0.339, I <sup>2</sup> =0%							P=0.342
Investigations	Blood glucose abnormal	Mild	0.7% (0.1, 4.6)	3.9% (1.1, 12.6)	P=0.973, I <sup>2</sup> =0%	P=0.339, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.025 (-0.060 - 0.009)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.342
Investigations	Blood glucose abnormal	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Blood glucose abnormal	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigation s	Blood thyroid stimulating hormone increased		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigation s	Blood thyroid stimulating hormone increased	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.992
Investigation s	Blood thyroid stimulating hormone increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Blood thyroid stimulating hormone increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	White blood cell count decreased		1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.536
Investigations	White blood cell count decreased	Mild	1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.729, I <sup>2</sup> =0%	P=0.536
Investigations	White blood cell count decreased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	White blood cell count decreased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Tri-iodothyronine free increased		1.1% (0.2, 5.2)	2.0% (0.4, 9.4)	P=0.653, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.996
Investigations	Tri-iodothyronine free increased	Mild	1.1% (0.2, 5.2)	2.0% (0.4, 9.4)	P=0.653, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	0.529 (0.032 - 8.695)	0.535 (0.034 - 8.319)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.996
Investigations	Tri-iodothyronine free increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Tri-iodothyronine free increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Blood urea increased		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.991
Investigations	Blood urea increased	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.991
Investigations	Blood urea increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Blood urea increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Electrocardiogram T wave peaked		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.592
Investigations	Electrocardiogram T wave peaked	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.592
Investigations	Electrocardiogram T wave peaked	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Electrocardiogram T wave peaked	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Blood cortisol decreased		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Blood cortisol decreased	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Investigations	Blood cortisol decreased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Blood cortisol decreased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Blood iron decreased		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.733
Investigations	Blood iron decreased	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.733

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Blood iron decreased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Blood iron decreased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Cortisol free urine decreased		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Investigations	Cortisol free urine decreased	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Cortisol free urine decreased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Cortisol free urine decreased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Thyroxine decreased		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.733
Investigations	Thyroxine decreased	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.733
Investigations	Thyroxine decreased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Thyroxine decreased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Transaminases increased		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Investigations	Transaminases increased	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Investigations	Transaminases increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Transaminases increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Blood cholesterol increased		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Investigations	Blood cholesterol increased	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Investigations	Blood cholesterol increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Blood cholesterol increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Electrocardiogram ST segment abnormal		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.732
Investigations	Electrocardiogram ST segment abnormal	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732
Investigations	Electrocardiogram ST segment abnormal	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Electrocardiogram ST segment abnormal	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Haemoglobin decreased		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Haemoglobin decreased	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732
Investigations	Haemoglobin decreased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Haemoglobin decreased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Hepatic enzyme abnormal		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Hepatic enzyme abnormal	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732
Investigations	Hepatic enzyme abnormal	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Hepatic enzyme abnormal	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Hepatic enzyme increased		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.732
Investigations	Hepatic enzyme increased	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Hepatic enzyme increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Hepatic enzyme increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Lipids increased		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.732
Investigations	Lipids increased	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732
Investigations	Lipids increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Lipids increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Liver function test abnormal		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.732
Investigations	Liver function test abnormal	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732
Investigations	Liver function test abnormal	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Liver function test abnormal	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Thyroid function test abnormal		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.732
Investigations	Thyroid function test abnormal	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigation s	Thyroid function test abnormal	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Investigation s	Thyroid function test abnormal	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Investigation s	Thyroxine free decreased		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.718
Investigation s	Thyroxine free decreased	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Investigation s	Thyroxine free decreased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Thyroxine free decreased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Basophil count increased		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Investigations	Basophil count increased	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Investigations	Basophil count increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Basophil count increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Blood lactate dehydrogenase increased		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.717
Investigations	Blood lactate dehydrogenase increased	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.717
Investigations	Blood lactate dehydrogenase increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Blood lactate dehydrogenase increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Blood potassium increased		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.717
Investigations	Blood potassium increased	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.717
Investigations	Blood potassium increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Blood potassium increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Blood pressure increased		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.717
Investigations	Blood pressure increased	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.717
Investigations	Blood pressure increased	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Blood pressure increased	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Electrocardiogram high voltage		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Investigations	Electrocardiogram high voltage	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Investigations	Electrocardiogram high voltage	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Investigations	Electrocardiogram high voltage	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Respiratory, thoracic and mediastinal disorders			28.7% (22.0, 36.6)	14.5% (8.2, 24.4)	P=0.322, I <sup>2</sup> =0%	P=0.273, I <sup>2</sup> =17%							P=0.080

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders		Mild	25.3% (18.8, 33.2)	14.5% (8.2, 24.4)	P=0.034, I <sup>2</sup> =77.9%	P=0.273, I <sup>2</sup> =17%	2.034 (0.963 - 4.296)	1.757 (0.953 - 3.238)	0.105 (0.003 - 0.207)	P=0.892, I <sup>2</sup> =0%	P=0.996, I <sup>2</sup> =0%	P=0.516, I <sup>2</sup> =0%	P=0.698
Respiratory, thoracic and mediastinal disorders		Moderate	6.5% (3.0, 13.4)	1.2% (0.2, 8.2)	P=0.091, I <sup>2</sup> =65.1%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.041 (0.009 - 0.073)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.067
Respiratory, thoracic and mediastinal disorders		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Cough		20.8% (14.7, 28.6)	4.1% (1.3, 11.9)	P=0.008, I <sup>2</sup> =85.6%	P=0.522, I <sup>2</sup> =0%							P=0.002
Respiratory, thoracic and mediastinal disorders	Cough	Mild	20.6% (14.4, 28.5)	4.1% (1.3, 11.9)	P=0.005, I <sup>2</sup> =87.6%	P=0.522, I <sup>2</sup> =0%	5.899 (1.719 - 20.241)	4.828 (1.521 - 15.323)	0.145 (0.071 - 0.220)	P=0.678, I <sup>2</sup> =0%	P=0.784, I <sup>2</sup> =0%	P=0.022, I <sup>2</sup> =8104%	P=0.017
Respiratory, thoracic and mediastinal disorders	Cough	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.221

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Cough	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea		2.1% (0.6, 7.0)	5.1% (1.9, 12.7)	P=0.349, I <sup>2</sup> =0%	P=0.938, I <sup>2</sup> =0%							P=0.717
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Mild	2.1% (0.6, 7.0)	5.1% (1.9, 12.7)	P=0.349, I <sup>2</sup> =0%	P=0.938, I <sup>2</sup> =0%	0.258 (0.046 - 1.450)	0.268 (0.050 - 1.432)	-0.037 (-0.089 - 0.015)	P=0.365, I <sup>2</sup> =0%	P=0.359, I <sup>2</sup> =0%	P=0.601, I <sup>2</sup> =0%	P=0.717

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic		2.2% (0.7, 6.6)	3.9% (1.1, 12.6)	P=0.530, I <sup>2</sup> =0%	P=0.339, I <sup>2</sup> =0%							P=0.913

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Mild	2.2% (0.7, 6.6)	3.9% (1.1, 12.6)	P=0.530, I <sup>2</sup> =0%	P=0.339, I <sup>2</sup> =0%	0.799 (0.130 - 4.915)	0.804 (0.139 - 4.670)	-0.005 (-0.046 - 0.036)	P=0.544, I <sup>2</sup> =0%	P=0.546, I <sup>2</sup> =0%	P=0.470, I <sup>2</sup> =0%	P=0.913
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Asthma		2.1% (0.6, 7.0)	1.2% (0.2, 8.2)	P=0.349, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.524
Respiratory, thoracic and mediastinal disorders	Asthma	Mild	2.1% (0.6, 7.0)	1.2% (0.2, 8.2)	P=0.349, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.537
Respiratory, thoracic and mediastinal disorders	Asthma	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.982

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Asthma	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Respiratory, thoracic and mediastinal disorders	Respiratory disorder		3.1% (1.1, 8.4)	2.0% (0.4, 9.2)	P=0.249, I <sup>2</sup> =24.7%	P=0.708, I <sup>2</sup> =0%							P=0.344
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Mild	2.0% (0.6, 6.7)	2.0% (0.4, 9.2)	P=0.395, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	1.081 (0.095 - 12.293)	1.079 (0.101 - 11.544)	0.001 (-0.030 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.765

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.448
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Respiratory, thoracic and mediastinal disorders	Epistaxis		2.0% (0.6, 6.7)	2.0% (0.4, 9.2)	P=0.395, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.929

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Epistaxis	Mild	1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	0.533 (0.032 - 8.755)	0.539 (0.035 - 8.402)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.701
Respiratory, thoracic and mediastinal disorders	Epistaxis	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Respiratory, thoracic and mediastinal disorders	Epistaxis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Nasal congestion		2.0% (0.6, 6.7)	2.5% (0.6, 9.6)	P=0.395, I <sup>2</sup> =0%	P=0.957, I <sup>2</sup> =0%							P=0.969
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Mild	1.1% (0.2, 5.1)	2.5% (0.6, 9.6)	P=0.711, I <sup>2</sup> =0%	P=0.957, I <sup>2</sup> =0%	0.265 (0.024 - 2.968)	0.269 (0.025 - 2.919)	-0.018 (-0.056 - 0.019)	P=0.581, I <sup>2</sup> =0%	P=0.580, I <sup>2</sup> =0%	P=0.630, I <sup>2</sup> =0%	P=0.795
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Respiratory, thoracic and mediastinal disorders	Wheezing		2.0% (0.6, 6.7)	2.0% (0.4, 9.2)	P=0.395, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.765
Respiratory, thoracic and mediastinal disorders	Wheezing	Mild	1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	0.533 (0.032 - 8.755)	0.539 (0.035 - 8.402)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.994

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Wheezing	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Respiratory, thoracic and mediastinal disorders	Wheezing	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Respiratory, thoracic and mediastinal disorders	Sinus congestion		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.849

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.592
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Allergic cough		1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.536
Respiratory, thoracic and mediastinal disorders	Allergic cough	Mild	1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.729, I <sup>2</sup> =0%	P=0.536
Respiratory, thoracic and mediastinal disorders	Allergic cough	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Allergic cough	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome		1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.536
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Laryngospasm		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Respiratory, thoracic and mediastinal disorders	Nasal obstruction		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Respiratory, thoracic and mediastinal disorders	Productive cough		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Productive cough	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Respiratory, thoracic and mediastinal disorders	Productive cough	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Respiratory, thoracic and mediastinal disorders	Productive cough	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Gastrointestinal disorders			21.1% (15.3, 28.5)	18.5% (11.2, 28.9)	P=0.694, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =42%							P=0.622



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Gastrointestinal disorders		Mild	20.4% (14.7, 27.7)	17.8% (10.5, 28.3)	P=0.841, I <sup>2</sup> =0%	P=0.105, I <sup>2</sup> =62%	1.300 (0.635 - 2.661)	1.240 (0.686 - 2.239)	0.039 (-0.065 - 0.144)	P=0.138, I <sup>2</sup> =5458%	P=0.135, I <sup>2</sup> =5520%	P=0.143, I <sup>2</sup> =5333%	P=0.792
Gastrointestinal disorders		Moderate	1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	0.533 (0.032 - 8.755)	0.539 (0.035 - 8.402)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.690
Gastrointestinal disorders		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Gastrointestinal disorders	Diarrhoea		6.2% (3.2, 11.5)	6.5% (2.7, 14.7)	P=0.654, I <sup>2</sup> =0%	P=0.586, I <sup>2</sup> =0%							P=0.532

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Gastrointestinal disorders	Diarrhoea	Mild	6.2% (3.2, 11.5)	6.5% (2.7, 14.7)	P=0.654, I <sup>2</sup> =0%	P=0.586, I <sup>2</sup> =0%	0.964 (0.311 - 2.987)	0.967 (0.336 - 2.782)	-0.002 (-0.068 - 0.064)	P=0.862, I <sup>2</sup> =0%	P=0.862, I <sup>2</sup> =0%	P=0.853, I <sup>2</sup> =0%	P=0.532
Gastrointestinal disorders	Diarrhoea	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Gastrointestinal disorders	Diarrhoea	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Gastrointestinal disorders	Vomiting		8.9% (4.6, 16.6)	3.7% (1.1, 12.1)	P=0.054, I <sup>2</sup> =73%	P=0.390, I <sup>2</sup> =0%							P=0.543

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Gastrointestinal disorders	Vomiting	Mild	8.9% (4.6, 16.6)	2.0% (0.4, 9.2)	P=0.054, I <sup>2</sup> =73%	P=0.708, I <sup>2</sup> =0%	4.706 (0.568 - 39.019)	4.316 (0.559 - 33.320)	0.042 (-0.002 - 0.086)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.392
Gastrointestinal disorders	Vomiting	Moderate	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.733
Gastrointestinal disorders	Vomiting	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Gastrointestinal disorders	Nausea		3.1% (1.1, 8.4)	2.0% (0.4, 9.2)	P=0.249, I <sup>2</sup> =24.7%	P=0.708, I <sup>2</sup> =0%							P=0.786
Gastrointestinal disorders	Nausea	Mild	2.0% (0.6, 6.7)	2.0% (0.4, 9.2)	P=0.395, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	1.081 (0.095 - 12.293)	1.079 (0.101 - 11.544)	0.001 (-0.030 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.705

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Gastrointesti nal disorders	Nausea	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.448
Gastrointesti nal disorders	Nausea	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Gastrointesti nal disorders	Abdominal pain		3.0% (1.1, 7.8)	2.0% (0.4, 9.2)	P=0.365 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%							P=0.254
Gastrointesti nal disorders	Abdominal pain	Mild	2.1% (0.7, 6.4)	2.0% (0.4, 9.2)	P=0.606 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%	1.632 (0.166 - 16.068)	1.616 (0.171 - 15.223)	0.008 (-0.026 - 0.041)	P=0.74 0, I <sup>2</sup> =0%	P=0.73 8, I <sup>2</sup> =0%	P=0.84 6, I <sup>2</sup> =0%	P=0.337

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Gastrointesti nal disorders	Abdominal pain	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.718
Gastrointesti nal disorders	Abdominal pain	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Gastrointesti nal disorders	Abdominal pain upper		2.7% (1.0, 7.0)	2.0% (0.4, 9.2)	P=0.945 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%							P=0.801
Gastrointesti nal disorders	Abdominal pain upper	Mild	2.7% (1.0, 7.0)	2.0% (0.4, 9.2)	P=0.945 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%	2.183 (0.239 - 19.909)	2.152 (0.244 - 18.974)	0.015 (-0.021 - 0.051)	P=0.55 7, I <sup>2</sup> =0%	P=0.55 5, I <sup>2</sup> =0%	P=0.62 3, I <sup>2</sup> =0%	P=0.801

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Gastrointesti nal disorders	Abdominal pain upper	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Gastrointesti nal disorders	Abdominal pain upper	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Gastrointesti nal disorders	Dyspepsia		2.2% (0.7, 6.6)	3.9% (1.1, 12.6)	P=0.530 , I <sup>2</sup> =0%	P=0.339 , I <sup>2</sup> =0%							P=0.810
Gastrointesti nal disorders	Dyspepsia	Mild	2.2% (0.7, 6.6)	3.9% (1.1, 12.6)	P=0.530 , I <sup>2</sup> =0%	P=0.339 , I <sup>2</sup> =0%	0.799 (0.130 - 4.915)	0.804 (0.139 - 4.670)	-0.005 (-0.046 - 0.036)	P=0.54 4, I <sup>2</sup> =0%	P=0.54 6, I <sup>2</sup> =0%	P=0.47 0, I <sup>2</sup> =0%	P=0.810
Gastrointesti nal disorders	Dyspepsia	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Gastrointestinal disorders	Dyspepsia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Gastrointestinal disorders	Constipation		1.1% (0.2, 5.1)	2.0% (0.4, 9.4)	P=0.711, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.550
Gastrointestinal disorders	Constipation	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.342
Gastrointestinal disorders	Constipation	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Gastrointestinal disorders	Constipation	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Gastrointestinal disorders	Toothache		1.1% (0.2, 5.2)	2.0% (0.4, 9.4)	P=0.653, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.985
Gastrointestinal disorders	Toothache	Mild	1.1% (0.2, 5.2)	2.0% (0.4, 9.4)	P=0.653, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	0.529 (0.032 - 8.695)	0.535 (0.034 - 8.319)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.985
Gastrointestinal disorders	Toothache	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Gastrointestinal disorders	Toothache	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Gastrointestinal disorders	Abdominal discomfort		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Gastrointestinal disorders	Abdominal discomfort	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.992
Gastrointestinal disorders	Abdominal discomfort	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Gastrointestinal disorders	Abdominal discomfort	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Gastrointestinal disorders	Enteritis		1.1% (0.2, 5.2)	2.0% (0.4, 9.4)	P=0.653, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.996

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Gastrointesti nal disorders	Enteritis	Mild	1.1% (0.2, 5.2)	2.0% (0.4, 9.4)	P=0.653 , I <sup>2</sup> =0%	P=0.644 , I <sup>2</sup> =0%	0.529 (0.032 - 8.695)	0.535 (0.034 - 8.319)	-0.006 (-0.034 - 0.022)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.996
Gastrointesti nal disorders	Enteritis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Gastrointesti nal disorders	Enteritis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Gastrointesti nal disorders	Gastrointesti nal disorder		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.993

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Gastrointestinal disorders	Gastrointestinal disorder	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.993
Gastrointestinal disorders	Gastrointestinal disorder	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Gastrointestinal disorders	Gastrointestinal disorder	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Gastrointestinal disorders	Aphthous ulcer		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.733
Gastrointestinal disorders	Aphthous ulcer	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.733

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Gastrointesti nal disorders	Aphthous ulcer	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Gastrointesti nal disorders	Aphthous ulcer	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Gastrointesti nal disorders	Gastric disorder		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.718
Gastrointesti nal disorders	Gastric disorder	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Gastrointesti nal disorders	Gastric disorder	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Gastrointesti nal disorders	Gastric disorder	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Gastrointesti nal disorders	Gastrointesti nal motility disorder		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.718
Gastrointesti nal disorders	Gastrointesti nal motility disorder	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.718
Gastrointesti nal disorders	Gastrointesti nal motility disorder	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Gastrointesti nal disorders	Gastrointesti nal motility disorder	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Gastrointesti nal disorders	Lip swelling		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.718
Gastrointesti nal disorders	Lip swelling	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.718
Gastrointesti nal disorders	Lip swelling	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Gastrointesti nal disorders	Lip swelling	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Gastrointestinal disorders	Abdominal distension		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Gastrointestinal disorders	Abdominal distension	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Gastrointestinal disorders	Abdominal distension	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Gastrointestinal disorders	Abdominal distension	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Gastrointesti nal disorders	Noninfective gingivitis		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973 , I <sup>2</sup> =0%	P=0.644 , I <sup>2</sup> =0%							P=0.732
Gastrointesti nal disorders	Noninfective gingivitis	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973 , I <sup>2</sup> =0%	P=0.644 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.732
Gastrointesti nal disorders	Noninfective gingivitis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Gastrointesti nal disorders	Noninfective gingivitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions			20.4% (14.7, 27.7)	20.9% (13.2, 31.5)	P=0.841 , I <sup>2</sup> =0%	P=0.202 , I <sup>2</sup> =39%							P=0.569
General disorders and administrati on site conditions		Mild	17.7% (12.3, 24.7)	19.4% (11.8, 30.3)	P=0.848 , I <sup>2</sup> =0%	P=0.063 , I <sup>2</sup> =71%	0.997 (0.486 - 2.042)	0.997 (0.554 - 1.796)	0.000 (-0.105 - 0.104)	P=0.150, I <sup>2</sup> =5175%	P=0.152, I <sup>2</sup> =5121%	P=0.134, I <sup>2</sup> =5539%	P=0.634
General disorders and administrati on site conditions		Moderate	3.0% (1.1, 7.8)	3.7% (1.1, 12.1)	P=0.365 , I <sup>2</sup> =0%	P=0.390 , I <sup>2</sup> =0%	1.081 (0.191 - 6.101)	1.078 (0.204 - 5.701)	0.002 (-0.041 - 0.045)	P=0.683, I <sup>2</sup> =0%	P=0.683, I <sup>2</sup> =0%	P=0.710, I <sup>2</sup> =0%	P=0.921

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administration site conditions		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
General disorders and administration site conditions	Pyrexia		17.1% (11.8, 24.0)	12.1% (6.4, 21.7)	P=0.637, I <sup>2</sup> =0%	P=0.247, I <sup>2</sup> =25%							P=0.532

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Pyrexia	Mild	15.0% (10.1, 21.7)	12.1% (6.4, 21.7)	P=0.863 , I <sup>2</sup> =0%	P=0.247 , I <sup>2</sup> =25%	1.369 (0.597 - 3.139)	1.313 (0.636 - 2.710)	0.036 (-0.055 - 0.126)	P=0.370, I <sup>2</sup> =0%	P=0.364, I <sup>2</sup> =0%	P=0.412, I <sup>2</sup> =0%	P=0.613
General disorders and administrati on site conditions	Pyrexia	Moderate	3.1% (1.1, 8.4)	1.2% (0.2, 8.2)	P=0.249 , I <sup>2</sup> =24.7%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.020 (-0.002 - 0.043)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.609
General disorders and administrati on site conditions	Pyrexia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Injection site pain		3.2% (1.1, 8.8)	1.2% (0.2, 8.2)	P=0.214 , I <sup>2</sup> =35.2 %	P=0.970 , I <sup>2</sup> =0%							P=0.493
General disorders and administrati on site conditions	Injection site pain	Mild	3.2% (1.1, 8.8)	1.2% (0.2, 8.2)	P=0.214 , I <sup>2</sup> =35.2 %	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.020 (-0.002 - 0.043)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.493

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Injection site pain	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
General disorders and administrati on site conditions	Injection site pain	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
General disorders and administrati on site conditions	Injection site pruritus		2.1% (0.6, 7.0)	2.0% (0.4, 9.4)	P=0.349 , I <sup>2</sup> =0%	P=0.644 , I <sup>2</sup> =0%							P=0.767

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Injection site pruritus	Mild	2.1% (0.6, 7.0)	2.0% (0.4, 9.4)	P=0.349 , I <sup>2</sup> =0%	P=0.644 , I <sup>2</sup> =0%	1.072 (0.094 - 12.224)	1.070 (0.100 - 11.427)	0.001 (-0.030 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.767
General disorders and administrati on site conditions	Injection site pruritus	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Injection site pruritus	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
General disorders and administrati on site conditions	Fatigue		1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%							P=0.994
General disorders and administrati on site conditions	Fatigue	Mild	1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%	0.533 (0.032 - 8.755)	0.539 (0.035 - 8.402)	-0.006 (-0.034 - 0.022)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.994

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administration site conditions	Fatigue	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
General disorders and administration site conditions	Fatigue	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Injection site swelling		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973 , I <sup>2</sup> =0%	P=0.644 , I <sup>2</sup> =0%							P=0.991
General disorders and administrati on site conditions	Injection site swelling	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973 , I <sup>2</sup> =0%	P=0.644 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.991
General disorders and administrati on site conditions	Injection site swelling	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administration site conditions	Injection site swelling	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
General disorders and administration site conditions	Injection site erythema		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.448

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Injection site erythema	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.448
General disorders and administrati on site conditions	Injection site erythema	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
General disorders and administrati on site conditions	Injection site erythema	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administration site conditions	Injection site reaction		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.993
General disorders and administration site conditions	Injection site reaction	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Injection site reaction	Moderate	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.718
General disorders and administrati on site conditions	Injection site reaction	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
General disorders and administrati on site conditions	Face oedema		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%							P=0.733

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Face oedema	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
General disorders and administrati on site conditions	Face oedema	Moderate	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.733

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Face oedema	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
General disorders and administrati on site conditions	Gait disturbance		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.718
General disorders and administrati on site conditions	Gait disturbance	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administration site conditions	Gait disturbance	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
General disorders and administration site conditions	Gait disturbance	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Influenza like illness		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%							P=0.733
General disorders and administrati on site conditions	Influenza like illness	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
General disorders and administrati on site conditions	Influenza like illness	Moderate	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.733

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administration site conditions	Influenza like illness	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
General disorders and administration site conditions	Injection site atrophy		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Injection site atrophy	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.718
General disorders and administrati on site conditions	Injection site atrophy	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
General disorders and administrati on site conditions	Injection site atrophy	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Injection site urticaria		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.718
General disorders and administrati on site conditions	Injection site urticaria	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administration site conditions	Injection site urticaria	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
General disorders and administration site conditions	Injection site urticaria	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
General disorders and administration site conditions	Medical device discomfort		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%							P=0.733

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Medical device discomfort	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.733
General disorders and administrati on site conditions	Medical device discomfort	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Medical device discomfort	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
General disorders and administrati on site conditions	Vaccination site pain		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%							P=0.733
General disorders and administrati on site conditions	Vaccination site pain	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.733

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Vaccination site pain	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
General disorders and administrati on site conditions	Vaccination site pain	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Injection site bruising		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973 , I <sup>2</sup> =0%	P=0.644 , I <sup>2</sup> =0%							P=0.732
General disorders and administrati on site conditions	Injection site bruising	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973 , I <sup>2</sup> =0%	P=0.644 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.732
General disorders and administrati on site conditions	Injection site bruising	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Injection site bruising	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
General disorders and administrati on site conditions	Pain		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973 , I <sup>2</sup> =0%	P=0.644 , I <sup>2</sup> =0%							P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Pain	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973 , I <sup>2</sup> =0%	P=0.644 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.732
General disorders and administrati on site conditions	Pain	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
General disorders and administrati on site conditions	Pain	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Peripheral swelling		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.718
General disorders and administrati on site conditions	Peripheral swelling	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Peripheral swelling	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
General disorders and administrati on site conditions	Peripheral swelling	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
General disorders and administrati on site conditions	Injection site haemorrhage		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.717

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administration site conditions	Injection site haemorrhage	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.717
General disorders and administration site conditions	Injection site haemorrhage	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
General disorders and administrati on site conditions	Injection site haemorrhage	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Nervous system disorders			8.4% (4.4, 15.3)	15.3% (8.9, 25.0)	P=0.050 , I <sup>2</sup> =74%	P=0.629 , I <sup>2</sup> =0%							P=0.225
Nervous system disorders		Mild	5.1% (2.3, 10.8)	12.7% (7.0, 22.0)	P=0.150 , I <sup>2</sup> =51.7%	P=0.898 , I <sup>2</sup> =0%	0.295 (0.103 - 0.846)	0.323 (0.122 - 0.856)	-0.086 (-0.166 - -0.006)	P=0.191, I <sup>2</sup> =4151%	P=0.182, I <sup>2</sup> =4375%	P=0.450, I <sup>2</sup> =0%	P=0.167
Nervous system disorders		Moderate	3.1% (1.1, 8.4)	3.7% (1.1, 12.1)	P=0.249 , I <sup>2</sup> =24.7%	P=0.390 , I <sup>2</sup> =0%	0.801 (0.128 - 5.000)	0.809 (0.141 - 4.649)	-0.005 (-0.046 - 0.036)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.790

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Nervous system disorders		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Nervous system disorders	Headache		8.9% (4.6, 16.6)	12.8% (7.0, 22.2)	P=0.054, I <sup>2</sup> =73%	P=0.585, I <sup>2</sup> =0%							P=0.461
Nervous system disorders	Headache	Mild	5.3% (2.3, 11.8)	10.1% (5.1, 19.0)	P=0.122, I <sup>2</sup> =58.2%	P=0.910, I <sup>2</sup> =0%	0.314 (0.099 - 1.000)	0.337 (0.114 - 0.995)	-0.067 (-0.140 - 0.006)	P=0.117, I <sup>2</sup> =594%	P=0.112, I <sup>2</sup> =604%	P=0.305, I <sup>2</sup> =491%	P=0.487
Nervous system disorders	Headache	Moderate	3.1% (1.1, 8.4)	3.7% (1.1, 12.1)	P=0.249, I <sup>2</sup> =24.7%	P=0.390, I <sup>2</sup> =0%	0.801 (0.128 - 5.000)	0.809 (0.141 - 4.649)	-0.005 (-0.046 - 0.036)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.790
Nervous system disorders	Headache	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Nervous system disorders	Dizziness		1.4% (0.3, 5.3)	2.5% (0.6, 9.6)	P=0.961, I <sup>2</sup> =0%	P=0.957, I <sup>2</sup> =0%							P=0.469
Nervous system disorders	Dizziness	Mild	1.4% (0.3, 5.3)	2.5% (0.6, 9.6)	P=0.961, I <sup>2</sup> =0%	P=0.957, I <sup>2</sup> =0%	0.531 (0.073 - 3.843)	0.537 (0.077 - 3.742)	-0.012 (-0.051 - 0.028)	P=0.996, I <sup>2</sup> =0%	P=0.997, I <sup>2</sup> =0%	P=0.980, I <sup>2</sup> =0%	P=0.469
Nervous system disorders	Dizziness	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Nervous system disorders	Dizziness	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Nervous system disorders	Post-traumatic headache		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.448
Nervous system disorders	Post-traumatic headache	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.448
Nervous system disorders	Post-traumatic headache	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Nervous system disorders	Post-traumatic headache	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Nervous system disorders	Migraine		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.733

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Nervous system disorders	Migraine	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.733
Nervous system disorders	Migraine	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Nervous system disorders	Migraine	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Nervous system disorders	Tremor		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Nervous system disorders	Tremor	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Nervous system disorders	Tremor	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Nervous system disorders	Tremor	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications			9.0% (5.3, 14.9)	9.4% (4.2, 19.4)	P=0.460, I <sup>2</sup> =0%	P=0.144, I <sup>2</sup> =53%							P=0.667

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications		Mild	6.1% (3.2, 11.4)	7.5% (3.1, 16.7)	P=0.811, I <sup>2</sup> =0%	P=0.225, I <sup>2</sup> =32%	0.966 (0.312 - 2.994)	0.968 (0.336 - 2.788)	-0.002 (-0.068 - 0.064)	P=0.358, I <sup>2</sup> =0%	P=0.360, I <sup>2</sup> =0%	P=0.312, I <sup>2</sup> =201%	P=0.763
Injury, poisoning and procedural complications		Moderate	3.0% (1.1, 7.8)	2.0% (0.4, 9.2)	P=0.365, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	2.203 (0.239 - 20.267)	2.155 (0.247 - 18.825)	0.015 (-0.021 - 0.050)	P=0.758, I <sup>2</sup> =0%	P=0.760, I <sup>2</sup> =0%	P=0.789, I <sup>2</sup> =0%	P=0.948
Injury, poisoning and procedural complications		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Head injury		1.4% (0.3, 5.3)	2.0% (0.4, 9.4)	P=0.961, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.784
Injury, poisoning and procedural complications	Head injury	Mild	1.4% (0.3, 5.3)	2.0% (0.4, 9.4)	P=0.961, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	1.074 (0.096 - 12.031)	1.073 (0.099 - 11.620)	0.001 (-0.030 - 0.032)	P=0.575, I <sup>2</sup> =0%	P=0.575, I <sup>2</sup> =0%	P=0.595, I <sup>2</sup> =0%	P=0.784
Injury, poisoning and procedural complications	Head injury	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Head injury	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Post-traumatic pain		1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.994
Injury, poisoning and procedural complications	Post-traumatic pain	Mild	1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	0.533 (0.032 - 8.755)	0.539 (0.035 - 8.402)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.994

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Post-traumatic pain	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Post-traumatic pain	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Animal bite		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%							P=0.461



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Animal bite	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.461
Injury, poisoning and procedural complications	Animal bite	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Animal bite	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Arthropod bite		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%							P=0.461
Injury, poisoning and procedural complications	Arthropod bite	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.461
Injury, poisoning and procedural complications	Arthropod bite	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Arthropod bite	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Contusion		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Contusion	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Contusion	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Injury, poisoning and procedural complications	Contusion	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Ligament sprain		1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.536

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Ligament sprain	Mild	1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.729, I <sup>2</sup> =0%	P=0.536
Injury, poisoning and procedural complications	Ligament sprain	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Ligament sprain	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Skin laceration		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.993
Injury, poisoning and procedural complications	Skin laceration	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Injury, poisoning and procedural complications	Skin laceration	Moderate	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Skin laceration	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Ankle fracture		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.718
Injury, poisoning and procedural complications	Ankle fracture	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Ankle fracture	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Injury, poisoning and procedural complications	Ankle fracture	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Concussion		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.733



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Concussion	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.733
Injury, poisoning and procedural complications	Concussion	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Concussion	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Face injury		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Injury, poisoning and procedural complications	Face injury	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Face injury	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Face injury	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Laceration		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Injury, poisoning and procedural complications	Laceration	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Laceration	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Laceration	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Meniscus injury		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%							P=0.733

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Meniscus injury	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Meniscus injury	Moderate	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.733
Injury, poisoning and procedural complications	Meniscus injury	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Radius fracture		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Injury, poisoning and procedural complications	Radius fracture	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Injury, poisoning and procedural complications	Radius fracture	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Radius fracture	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Thermal burn		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.733
Injury, poisoning and procedural complications	Thermal burn	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.733

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Thermal burn	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Thermal burn	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Upper limb fracture		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.718



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Upper limb fracture	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Injury, poisoning and procedural complications	Upper limb fracture	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Upper limb fracture	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Burns first degree		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.717
Injury, poisoning and procedural complications	Burns first degree	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.717
Injury, poisoning and procedural complications	Burns first degree	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Burns first degree	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Burns second degree		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.732
Injury, poisoning and procedural complications	Burns second degree	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Burns second degree	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.732
Injury, poisoning and procedural complications	Burns second degree	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Fall		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Fall	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.732
Injury, poisoning and procedural complications	Fall	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Fall	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Muscle strain		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.732
Injury, poisoning and procedural complications	Muscle strain	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Muscle strain	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Muscle strain	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Wrist fracture		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.732
Injury, poisoning and procedural complications	Wrist fracture	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Wrist fracture	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Wrist fracture	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Eye injury		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.718



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Eye injury	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Injury, poisoning and procedural complications	Eye injury	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Eye injury	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Joint injury		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Injury, poisoning and procedural complications	Joint injury	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Injury, poisoning and procedural complications	Joint injury	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Joint injury	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Animal scratch		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.717
Injury, poisoning and procedural complications	Animal scratch	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.717

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Injury, poisoning and procedural complications	Animal scratch	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Injury, poisoning and procedural complications	Animal scratch	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Skin and subcutaneous tissue disorders			11.0% (6.9, 17.2)	7.9% (3.6, 16.5)	P=0.502 , I <sup>2</sup> =0%	P=0.458 , I <sup>2</sup> =0%							P=0.715
Skin and subcutaneous tissue disorders		Mild	10.5% (6.4, 16.6)	5.1% (1.9, 12.7)	P=0.343 , I <sup>2</sup> =0%	P=0.938 , I <sup>2</sup> =0%	2.130 (0.682 - 6.652)	2.014 (0.692 - 5.862)	0.051 (-0.017 - 0.120)	P=0.701, I <sup>2</sup> =0%	P=0.716, I <sup>2</sup> =0%	P=0.529, I <sup>2</sup> =0%	P=0.968

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Skin and subcutaneous tissue disorders		Moderate	1.1% (0.2, 5.1)	3.7% (1.1, 12.1)	P=0.711, I <sup>2</sup> =0%	P=0.390, I <sup>2</sup> =0%	0.260 (0.023 - 2.958)	0.270 (0.025 - 2.886)	-0.018 (-0.055 - 0.018)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.776
Skin and subcutaneous tissue disorders		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Skin and subcutaneous tissue disorders	Rash		1.1% (0.2, 5.1)	2.5% (0.6, 9.6)	P=0.711, I <sup>2</sup> =0%	P=0.957, I <sup>2</sup> =0%							P=0.360

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Skin and subcutaneous tissue disorders	Rash	Mild	1.1% (0.2, 5.1)	2.5% (0.6, 9.6)	P=0.711, I <sup>2</sup> =0%	P=0.957, I <sup>2</sup> =0%	0.265 (0.024 - 2.968)	0.269 (0.025 - 2.919)	-0.018 (-0.056 - 0.019)	P=0.581, I <sup>2</sup> =0%	P=0.580, I <sup>2</sup> =0%	P=0.630, I <sup>2</sup> =0%	P=0.360
Skin and subcutaneous tissue disorders	Rash	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Skin and subcutaneous tissue disorders	Rash	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Skin and subcutaneous tissue disorders	Urticaria		3.1% (1.2, 8.1)	2.0% (0.4, 9.2)	P=0.305, I <sup>2</sup> =4.9%	P=0.708, I <sup>2</sup> =0%							P=0.595

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Skin and subcutaneous tissue disorders	Urticaria	Mild	3.1% (1.2, 8.1)	1.2% (0.2, 8.2)	P=0.305, I <sup>2</sup> =4.9%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.027 (0.001 - 0.053)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.370, I <sup>2</sup> =0%	P=0.376
Skin and subcutaneous tissue disorders	Urticaria	Moderate	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.733
Skin and subcutaneous tissue disorders	Urticaria	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Skin and subcutaneous tissue disorders	Dermatitis allergic		2.1% (0.6, 7.0)	2.5% (0.6, 9.6)	P=0.349, I <sup>2</sup> =0%	P=0.957, I <sup>2</sup> =0%							P=0.970

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Skin and subcutaneous tissue disorders	Dermatitis allergic	Mild	2.1% (0.6, 7.0)	2.5% (0.6, 9.6)	P=0.349, I <sup>2</sup> =0%	P=0.957, I <sup>2</sup> =0%	0.529 (0.073 - 3.850)	0.536 (0.077 - 3.737)	-0.012 (-0.051 - 0.028)	P=0.380, I <sup>2</sup> =0%	P=0.380, I <sup>2</sup> =0%	P=0.474, I <sup>2</sup> =0%	P=0.970
Skin and subcutaneous tissue disorders	Dermatitis allergic	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Skin and subcutaneous tissue disorders	Dermatitis allergic	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Skin and subcutaneous tissue disorders	Eczema		2.2% (0.7, 6.6)	1.2% (0.2, 8.2)	P=0.530, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.438



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Skin and subcutaneous tissue disorders	Eczema	Mild	2.1% (0.6, 7.0)	1.2% (0.2, 8.2)	P=0.349, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.579
Skin and subcutaneous tissue disorders	Eczema	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Skin and subcutaneous tissue disorders	Eczema	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Skin and subcutaneous tissue disorders	Dermatitis contact		1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.536
Skin and subcutaneous tissue disorders	Dermatitis contact	Mild	1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.729, I <sup>2</sup> =0%	P=0.536
Skin and subcutaneous tissue disorders	Dermatitis contact	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Skin and subcutaneous tissue disorders	Dermatitis contact	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Skin and subcutaneous tissue disorders	Urticaria papular		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.993
Skin and subcutaneous tissue disorders	Urticaria papular	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.993
Skin and subcutaneous tissue disorders	Urticaria papular	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Skin and subcutaneous tissue disorders	Urticaria papular	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Skin and subcutaneous tissue disorders	Cafe au lait spots		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Skin and subcutaneous tissue disorders	Cafe au lait spots	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Skin and subcutaneous tissue disorders	Cafe au lait spots	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Skin and subcutaneous tissue disorders	Cafe au lait spots	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Skin and subcutaneous tissue disorders	Keratosis pilaris		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Skin and subcutaneous tissue disorders	Keratosis pilaris	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Skin and subcutaneous tissue disorders	Keratosis pilaris	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Skin and subcutaneous tissue disorders	Keratosis pilaris	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Skin and subcutaneous tissue disorders	Petechiae		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Skin and subcutaneous tissue disorders	Petechiae	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Skin and subcutaneous tissue disorders	Petechiae	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Skin and subcutaneous tissue disorders	Petechiae	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Skin and subcutaneous tissue disorders	Pityriasis alba		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Skin and subcutaneous tissue disorders	Pityriasis alba	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Skin and subcutaneous tissue disorders	Pityriasis alba	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Skin and subcutaneous tissue disorders	Pityriasis alba	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Skin and subcutaneous tissue disorders	Rash erythematous		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Skin and subcutaneous tissue disorders	Rash erythematous	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Skin and subcutaneous tissue disorders	Rash erythematous	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Skin and subcutaneous tissue disorders	Rash erythematous	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Skin and subcutaneous tissue disorders	Rash pruritic		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.733
Skin and subcutaneous tissue disorders	Rash pruritic	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Skin and subcutaneous tissue disorders	Rash pruritic	Moderate	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.733
Skin and subcutaneous tissue disorders	Rash pruritic	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Skin and subcutaneous tissue disorders	Dermatitis		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Skin and subcutaneous tissue disorders	Dermatitis	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Skin and subcutaneous tissue disorders	Dermatitis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Skin and subcutaneous tissue disorders	Dermatitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Skin and subcutaneous tissue disorders	Dyshidrotic eczema		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Skin and subcutaneous tissue disorders	Urticaria chronic		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Skin and subcutaneous tissue disorders	Urticaria chronic	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Skin and subcutaneous tissue disorders	Urticaria chronic	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Skin and subcutaneous tissue disorders	Urticaria chronic	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders			9.6% (5.6, 15.9)	6.5% (2.7, 14.7)	P=0.125, I <sup>2</sup> =57.6%	P=0.586, I <sup>2</sup> =0%							P=0.828
Eye disorders		Mild	8.7% (5.0, 14.7)	6.5% (2.7, 14.7)	P=0.194, I <sup>2</sup> =40.8%	P=0.586, I <sup>2</sup> =0%	1.316 (0.445 - 3.893)	1.288 (0.472 - 3.514)	0.018 (-0.051 - 0.088)	P=0.783, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	P=0.665, I <sup>2</sup> =0%	P=0.881

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Eye disorders		Moderate	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Eye disorders		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders	Refraction disorder		2.1% (0.6, 7.0)	3.9% (1.1, 12.6)	P=0.349, I <sup>2</sup> =0%	P=0.339, I <sup>2</sup> =0%							P=0.667
Eye disorders	Refraction disorder	Mild	2.1% (0.6, 7.0)	3.9% (1.1, 12.6)	P=0.349, I <sup>2</sup> =0%	P=0.339, I <sup>2</sup> =0%	0.522 (0.071 - 3.859)	0.535 (0.078 - 3.651)	-0.012 (-0.051 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.667

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Eye disorders	Refraction disorder	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders	Refraction disorder	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders	Strabismus		1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.994
Eye disorders	Strabismus	Mild	1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	0.533 (0.032 - 8.755)	0.539 (0.035 - 8.402)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.994
Eye disorders	Strabismus	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Eye disorders	Strabismus	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders	Conjunctivitis allergic		1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.536
Eye disorders	Conjunctivitis allergic	Mild	1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.729, I <sup>2</sup> =0%	P=0.536
Eye disorders	Conjunctivitis allergic	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Eye disorders	Conjunctivitis allergic	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders	Eye swelling		1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.536
Eye disorders	Eye swelling	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Eye disorders	Eye swelling	Moderate	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Eye disorders	Eye swelling	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Eye disorders	Myopia		1.1% (0.2, 5.2)	2.0% (0.4, 9.2)	P=0.653, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.991
Eye disorders	Myopia	Mild	1.1% (0.2, 5.2)	2.0% (0.4, 9.2)	P=0.653, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	0.537 (0.033 - 8.607)	0.537 (0.033 - 8.628)	-0.006 (-0.034 - 0.022)	P=0.338, I <sup>2</sup> =0%	P=0.339, I <sup>2</sup> =0%	P=0.337, I <sup>2</sup> =0%	P=0.991
Eye disorders	Myopia	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders	Myopia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Eye disorders	Papilloedema		1.1% (0.2, 5.2)	2.0% (0.4, 9.4)	P=0.653, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.996
Eye disorders	Papilloedema	Mild	1.1% (0.2, 5.2)	2.0% (0.4, 9.4)	P=0.653, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	0.529 (0.032 - 8.695)	0.535 (0.034 - 8.319)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.996
Eye disorders	Papilloedema	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders	Papilloedema	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders	Hypermetropia		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Eye disorders	Hypermetropia	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Eye disorders	Hypermetropia	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders	Hypermetropia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders	Astigmatism		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Eye disorders	Astigmatism	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Eye disorders	Astigmatism	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders	Astigmatism	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders	Eye haemorrhage		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Eye disorders	Eye haemorrhage	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Eye disorders	Eye haemorrhage	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Eye disorders	Eye haemorrhage	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders	Corneal epithelium defect		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Eye disorders	Corneal epithelium defect	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Eye disorders	Corneal epithelium defect	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Eye disorders	Corneal epithelium defect	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders	Eye pain		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Eye disorders	Eye pain	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Eye disorders	Eye pain	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders	Eye pain	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Eye disorders	Vitreous opacities		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Eye disorders	Vitreous opacities	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Eye disorders	Vitreous opacities	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders	Vitreous opacities	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders	Xerophthalmia		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.732



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Eye disorders	Xerophthalmia	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732
Eye disorders	Xerophthalmia	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders	Xerophthalmia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders	Vernal keratoconjunctivitis		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.717

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Eye disorders	Vernal keratoconjunctivitis	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.717
Eye disorders	Vernal keratoconjunctivitis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Eye disorders	Vernal keratoconjunctivitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Musculoskeletal and connective tissue disorders			8.2% (4.6, 14.2)	7.7% (3.1, 18.1)	P=0.160, I <sup>2</sup> =49.3%	P=0.163, I <sup>2</sup> =49%							P=0.651

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Musculoskeletal and connective tissue disorders		Mild	6.4% (3.4, 11.8)	7.7% (3.1, 18.1)	P=0.361, I <sup>2</sup> =0%	P=0.163, I <sup>2</sup> =49%	1.230 (0.362 - 4.176)	1.212 (0.389 - 3.777)	0.011 (-0.051 - 0.072)	P=0.317, I <sup>2</sup> =21%	P=0.315, I <sup>2</sup> =92%	P=0.335, I <sup>2</sup> =0%	P=0.831
Musculoskeletal and connective tissue disorders		Moderate	2.0% (0.6, 6.7)	1.2% (0.2, 8.2)	P=0.395, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.579
Musculoskeletal and connective tissue disorders		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Musculoskeletal and connective tissue disorders	Pain in extremity		4.0% (1.7, 9.3)	3.7% (1.1, 12.1)	P=0.230, I <sup>2</sup> =30.7%	P=0.390, I <sup>2</sup> =0%							P=0.400
Musculoskeletal and connective tissue disorders	Pain in extremity	Mild	3.0% (1.1, 7.8)	3.7% (1.1, 12.1)	P=0.365, I <sup>2</sup> =0%	P=0.390, I <sup>2</sup> =0%	1.081 (0.191 - 6.101)	1.078 (0.204 - 5.701)	0.002 (-0.041 - 0.045)	P=0.683, I <sup>2</sup> =0%	P=0.683, I <sup>2</sup> =0%	P=0.710, I <sup>2</sup> =0%	P=0.501
Musculoskeletal and connective tissue disorders	Pain in extremity	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Musculoskel etal and connective tissue disorders	Pain in extremity	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Musculoskel etal and connective tissue disorders	Arthralgia		3.0% (1.1, 7.8)	2.0% (0.4, 9.2)	P=0.365 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%							P=0.859
Musculoskel etal and connective tissue disorders	Arthralgia	Mild	3.0% (1.1, 7.8)	2.0% (0.4, 9.2)	P=0.365 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%	2.203 (0.239 - 20.267)	2.155 (0.247 - 18.825)	0.015 (-0.021 - 0.050)	P=0.758, I <sup>2</sup> =0%	P=0.760, I <sup>2</sup> =0%	P=0.789, I <sup>2</sup> =0%	P=0.859

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Musculoskel etal and connective tissue disorders	Arthralgia	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Musculoskel etal and connective tissue disorders	Arthralgia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Musculoskel etal and connective tissue disorders	Musculoskel etal pain		2.0% (0.6, 6.7)	1.2% (0.2, 8.2)	P=0.395 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.579

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Musculoskeletal and connective tissue disorders	Neck pain		1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.994
Musculoskeletal and connective tissue disorders	Neck pain	Mild	1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	0.533 (0.032 - 8.755)	0.539 (0.035 - 8.402)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.994
Musculoskeletal and connective tissue disorders	Neck pain	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Musculoskeletal and connective tissue disorders	Neck pain	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Musculoskeletal and connective tissue disorders	Arthritis reactive		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Musculoskeletal and connective tissue disorders	Arthritis reactive	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Musculoskeletal and connective tissue disorders	Arthritis reactive	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Musculoskeletal and connective tissue disorders	Arthritis reactive	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Musculoskeletal and connective tissue disorders	Back pain		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Musculoskeletal and connective tissue disorders	Back pain	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Musculoskeletal and connective tissue disorders	Back pain	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Musculoskeletal and connective tissue disorders	Back pain	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Musculoskeletal and connective tissue disorders	Neck mass		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Musculoskeletal and connective tissue disorders	Neck mass	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Musculoskeletal and connective tissue disorders	Neck mass	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Musculoskel etal and connective tissue disorders	Neck mass	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Musculoskel etal and connective tissue disorders	Pain in jaw		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.718
Musculoskel etal and connective tissue disorders	Pain in jaw	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Musculoskeletal and connective tissue disorders	Pain in jaw	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Musculoskeletal and connective tissue disorders	Pain in jaw	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Musculoskeletal and connective tissue disorders	Synovial cyst		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.733

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Musculoskel etal and connective tissue disorders	Synovial cyst	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.733
Musculoskel etal and connective tissue disorders	Synovial cyst	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Musculoskel etal and connective tissue disorders	Synovial cyst	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Musculoskeletal and connective tissue disorders	Scoliosis		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Musculoskeletal and connective tissue disorders	Scoliosis	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Musculoskeletal and connective tissue disorders	Scoliosis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Musculoskeletal and connective tissue disorders	Scoliosis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Metabolism and nutrition disorders			6.4% (3.1, 12.9)	12.8% (6.0, 25.2)	P=0.077, I <sup>2</sup> =68.1%	P=0.066, I <sup>2</sup> =71%							P=0.348
Metabolism and nutrition disorders		Mild	6.4% (3.1, 12.9)	12.8% (6.0, 25.2)	P=0.077, I <sup>2</sup> =68.1%	P=0.066, I <sup>2</sup> =71%	0.590 (0.186 - 1.874)	0.625 (0.224 - 1.746)	-0.029 (-0.095 - 0.038)	P=0.490, I <sup>2</sup> =0%	P=0.510, I <sup>2</sup> =0%	P=0.088, I <sup>2</sup> =6560%	P=0.348
Metabolism and nutrition disorders		Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Metabolism and nutrition disorders		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Metabolism and nutrition disorders	Hypertriglyceridaemia		4.4% (1.8, 10.6)	3.9% (1.1, 12.6)	P=0.143, I <sup>2</sup> =53.4%	P=0.339, I <sup>2</sup> =0%							P=0.645
Metabolism and nutrition disorders	Hypertriglyceridaemia	Mild	4.4% (1.8, 10.6)	3.9% (1.1, 12.6)	P=0.143, I <sup>2</sup> =53.4%	P=0.339, I <sup>2</sup> =0%	1.075 (0.188 - 6.153)	1.070 (0.205 - 5.579)	0.002 (-0.041 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.645
Metabolism and nutrition disorders	Hypertriglyceridaemia	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Metabolism and nutrition disorders	Hypertriglyceridaemia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Metabolism and nutrition disorders	Hypercholesterolaemia		1.1% (0.2, 5.2)	2.0% (0.4, 9.4)	P=0.653, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.981
Metabolism and nutrition disorders	Hypercholesterolaemia	Mild	1.1% (0.2, 5.2)	2.0% (0.4, 9.4)	P=0.653, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	0.529 (0.032 - 8.695)	0.535 (0.034 - 8.319)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.981

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Metabolism and nutrition disorders	Hypercholesterolaemia	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Metabolism and nutrition disorders	Hypercholesterolaemia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Metabolism and nutrition disorders	Hyperuricaemia		1.1% (0.2, 5.2)	2.0% (0.4, 9.4)	P=0.653, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.700
Metabolism and nutrition disorders	Hyperuricaemia	Mild	1.1% (0.2, 5.2)	2.0% (0.4, 9.4)	P=0.653, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	0.529 (0.032 - 8.695)	0.535 (0.034 - 8.319)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.700

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Metabolism and nutrition disorders	Hyperuricaemia	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Metabolism and nutrition disorders	Hyperuricaemia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Metabolism and nutrition disorders	Decreased appetite		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.679
Metabolism and nutrition disorders	Decreased appetite	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.679

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Metabolism and nutrition disorders	Decreased appetite	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Metabolism and nutrition disorders	Decreased appetite	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Metabolism and nutrition disorders	Polydipsia		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Metabolism and nutrition disorders	Polydipsia	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Metabolism and nutrition disorders	Polydipsia	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Metabolism and nutrition disorders	Polydipsia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Metabolism and nutrition disorders	Calcium deficiency		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Metabolism and nutrition disorders	Calcium deficiency	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732
Metabolism and nutrition disorders	Calcium deficiency	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Metabolism and nutrition disorders	Calcium deficiency	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Metabolism and nutrition disorders	Hyperglycaemia		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.732



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Metabolism and nutrition disorders	Hyperglycaemia	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732
Metabolism and nutrition disorders	Hyperglycaemia	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Metabolism and nutrition disorders	Hyperglycaemia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Metabolism and nutrition disorders	Hyperlipidaemia		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.732

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Metabolism and nutrition disorders	Hyperlipidaemia	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732
Metabolism and nutrition disorders	Hyperlipidaemia	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Metabolism and nutrition disorders	Hyperlipidaemia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Endocrine disorders			6.1% (3.1, 11.7)	7.5% (3.1, 16.7)	P=0.194, I <sup>2</sup> =40.8%	P=0.225, I <sup>2</sup> =32%							P=0.868

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Endocrine disorders		Mild	6.1% (3.1, 11.7)	7.5% (3.1, 16.7)	P=0.194, I <sup>2</sup> =40.8%	P=0.225, I <sup>2</sup> =32%	0.851 (0.266 - 2.721)	0.862 (0.294 - 2.523)	-0.009 (-0.073 - 0.056)	P=0.831, I <sup>2</sup> =0%	P=0.836, I <sup>2</sup> =0%	P=0.711, I <sup>2</sup> =0%	P=0.382
Endocrine disorders		Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.592
Endocrine disorders		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Endocrine disorders	Secondary hypothyroidism		5.3% (2.3, 11.8)	3.7% (1.1, 12.1)	P=0.122, I <sup>2</sup> =58.2%	P=0.390, I <sup>2</sup> =0%							P=0.807

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Endocrine disorders	Secondary hypothyroidism	Mild	5.3% (2.3, 11.8)	3.7% (1.1, 12.1)	P=0.122, I <sup>2</sup> =58.2%	P=0.390, I <sup>2</sup> =0%	1.373 (0.254 - 7.410)	1.349 (0.274 - 6.648)	0.009 (-0.036 - 0.054)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.547
Endocrine disorders	Secondary hypothyroidism	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Endocrine disorders	Secondary hypothyroidism	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Endocrine disorders	Hypothyroidism		2.1% (0.6, 7.0)	1.2% (0.2, 8.2)	P=0.349, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.332
Endocrine disorders	Hypothyroidism	Mild	2.1% (0.6, 7.0)	1.2% (0.2, 8.2)	P=0.349, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.332

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Endocrine disorders	Hypothyroid ism	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Endocrine disorders	Hypothyroid ism	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Endocrine disorders	Diabetes insipidus		1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%							P=0.994
Endocrine disorders	Diabetes insipidus	Mild	1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%	0.533 (0.032 - 8.755)	0.539 (0.035 - 8.402)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.994
Endocrine disorders	Diabetes insipidus	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Endocrine disorders	Diabetes insipidus	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Endocrine disorders	Secondary adrenocortical insufficiency		1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.994
Endocrine disorders	Secondary adrenocortical insufficiency	Mild	1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	0.533 (0.032 - 8.755)	0.539 (0.035 - 8.402)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.994
Endocrine disorders	Secondary adrenocortical insufficiency	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Endocrine disorders	Secondary adrenocortical insufficiency	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Endocrine disorders	Adrenal insufficiency		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Endocrine disorders	Adrenal insufficiency	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Endocrine disorders	Adrenal insufficiency	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Endocrine disorders	Adrenal insufficiency	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Endocrine disorders	Precocious puberty		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.732
Endocrine disorders	Precocious puberty	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732
Endocrine disorders	Precocious puberty	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Endocrine disorders	Precocious puberty	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Blood and lymphatic system disorders			6.9% (3.7, 12.3)	2.0% (0.4, 9.4)	P=0.588, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.126



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Blood and lymphatic system disorders		Mild	4.8% (2.3, 9.7)	2.0% (0.4, 9.4)	P=0.768 , I <sup>2</sup> =0%	P=0.644 , I <sup>2</sup> =0%	3.879 (0.470 - 32.035)	3.758 (0.471 - 30.004)	0.035 (-0.007 - 0.077)	P=0.446, I <sup>2</sup> =0%	P=0.442, I <sup>2</sup> =0%	P=0.514, I <sup>2</sup> =0%	P=0.208
Blood and lymphatic system disorders		Moderate	2.1% (0.7, 6.4)	1.2% (0.2, 8.2)	P=0.606 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.020 (-0.002 - 0.043)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.615, I <sup>2</sup> =0%	P=0.438
Blood and lymphatic system disorders		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Blood and lymphatic system disorders	Anaemia		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.923
Blood and lymphatic system disorders	Anaemia	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.923
Blood and lymphatic system disorders	Anaemia	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Blood and lymphatic system disorders	Anaemia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Blood and lymphatic system disorders	Iron deficiency anaemia		3.1% (1.1, 8.4)	1.2% (0.2, 8.2)	P=0.249 , I <sup>2</sup> =24.7%	P=0.970 , I <sup>2</sup> =0%							P=0.493
Blood and lymphatic system disorders	Iron deficiency anaemia	Mild	2.0% (0.6, 6.7)	1.2% (0.2, 8.2)	P=0.395 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.579
Blood and lymphatic system disorders	Iron deficiency anaemia	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Blood and lymphatic system disorders	Iron deficiency anaemia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Blood and lymphatic system disorders	Neutropenia		2.0% (0.6, 6.7)	1.2% (0.2, 8.2)	P=0.395, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.579
Blood and lymphatic system disorders	Neutropenia	Mild	2.0% (0.6, 6.7)	1.2% (0.2, 8.2)	P=0.395, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.579
Blood and lymphatic system disorders	Neutropenia	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Blood and lymphatic system disorders	Neutropenia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Blood and lymphatic system disorders	Lymphaden opathy		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.448
Blood and lymphatic system disorders	Lymphaden opathy	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.717
Blood and lymphatic system disorders	Lymphaden opathy	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Blood and lymphatic system disorders	Lymphaden opathy	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Blood and lymphatic system disorders	Granulocyto penia		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.993
Blood and lymphatic system disorders	Granulocyto penia	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.993
Blood and lymphatic system disorders	Granulocyto penia	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Blood and lymphatic system disorders	Granulocytopenia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Blood and lymphatic system disorders	Lymphadenitis		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.993
Blood and lymphatic system disorders	Lymphadenitis	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.993
Blood and lymphatic system disorders	Lymphadenitis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Blood and lymphatic system disorders	Lymphadenitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Blood and lymphatic system disorders	Hypochromic anaemia		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Blood and lymphatic system disorders	Hypochromic anaemia	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Blood and lymphatic system disorders	Hypochromic anaemia	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Blood and lymphatic system disorders	Hypochromic anaemia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Blood and lymphatic system disorders	Thymus disorder		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Blood and lymphatic system disorders	Thymus disorder	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Blood and lymphatic system disorders	Thymus disorder	Moderate	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Blood and lymphatic system disorders	Thymus disorder	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Immune system disorders			6.1% (2.9, 12.3)	2.0% (0.4, 9.2)	P=0.101 , I <sup>2</sup> =62.8%	P=0.708 , I <sup>2</sup> =0%							P=0.129
Immune system disorders		Mild	5.1% (2.3, 10.8)	2.0% (0.4, 9.2)	P=0.150 , I <sup>2</sup> =51.7%	P=0.708 , I <sup>2</sup> =0%	3.391 (0.395 - 29.122)	3.234 (0.400 - 26.120)	0.028 (-0.012 - 0.068)	P=0.636, I <sup>2</sup> =0%	P=0.648, I <sup>2</sup> =0%	P=0.372, I <sup>2</sup> =0%	P=0.157

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Immune system disorders		Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Immune system disorders		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Immune system disorders	Seasonal allergy		4.2% (1.7, 10.1)	1.2% (0.2, 8.2)	P=0.170, I <sup>2</sup> =47%	P=0.970, I <sup>2</sup> =0%							P=0.222
Immune system disorders	Seasonal allergy	Mild	4.2% (1.7, 10.1)	1.2% (0.2, 8.2)	P=0.170, I <sup>2</sup> =47%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.027 (0.001 - 0.054)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.222
Immune system disorders	Seasonal allergy	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Immune system disorders	Seasonal allergy	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Immune system disorders	Hypersensitivity		1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.690
Immune system disorders	Hypersensitivity	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.990
Immune system disorders	Hypersensitivity	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Immune system disorders	Hypersensitivity	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Immune system disorders	Allergy to animal		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Immune system disorders	Allergy to animal	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.992
Immune system disorders	Allergy to animal	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Immune system disorders	Allergy to animal	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Immune system disorders	Food allergy		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Immune system disorders	Food allergy	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Immune system disorders	Food allergy	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Immune system disorders	Food allergy	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Reproductive system and breast disorders			3.2% (1.1, 8.8)	3.7% (1.1, 12.1)	P=0.214, I <sup>2</sup> =35.2%	P=0.390, I <sup>2</sup> =0%							P=0.629
Reproductive system and breast disorders		Mild	3.2% (1.1, 8.8)	3.7% (1.1, 12.1)	P=0.214, I <sup>2</sup> =35.2%	P=0.390, I <sup>2</sup> =0%	0.805 (0.134 - 4.831)	0.805 (0.134 - 4.834)	-0.005 (-0.047 - 0.037)	P=0.094, I <sup>2</sup> =6443%	P=0.097, I <sup>2</sup> =6376%	P=0.067, I <sup>2</sup> =7013%	P=0.629
Reproductive system and breast disorders		Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Reproductive system and breast disorders		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Reproductive system and breast disorders	Penile adhesion		0.7% (0.1, 4.6)	3.7% (1.1, 12.1)	P=0.973, I <sup>2</sup> =0%	P=0.390, I <sup>2</sup> =0%							P=0.594
Reproductive system and breast disorders	Penile adhesion	Mild	0.7% (0.1, 4.6)	3.7% (1.1, 12.1)	P=0.973, I <sup>2</sup> =0%	P=0.390, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.025 (-0.060 - 0.009)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.594
Reproductive system and breast disorders	Penile adhesion	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Reproductive system and breast disorders	Penile adhesion	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Reproductive system and breast disorders	Gynaecomastia		2.1% (0.6, 7.0)	1.2% (0.2, 8.2)	P=0.349, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.579
Reproductive system and breast disorders	Gynaecomastia	Mild	2.1% (0.6, 7.0)	1.2% (0.2, 8.2)	P=0.349, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.579
Reproductive system and breast disorders	Gynaecomastia	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Reproductive system and breast disorders	Gynaecomastia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Reproductive system and breast disorders	Genital discomfort		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.733
Reproductive system and breast disorders	Genital discomfort	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.733
Reproductive system and breast disorders	Genital discomfort	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Reproductiv e system and breast disorders	Genital discomfort	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Reproductiv e system and breast disorders	Balanoposth itis		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.718
Reproductiv e system and breast disorders	Balanoposth itis	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.718
Reproductiv e system and breast disorders	Balanoposth itis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Reproductive system and breast disorders	Balanoposthitis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Reproductive system and breast disorders	Pelvic fluid collection		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Reproductive system and breast disorders	Pelvic fluid collection	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Reproductive system and breast disorders	Pelvic fluid collection	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Reproductive system and breast disorders	Pelvic fluid collection	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Reproductive system and breast disorders	Testicular appendage torsion		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Reproductive system and breast disorders	Testicular appendage torsion	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Reproductive system and breast disorders	Testicular appendage torsion	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Reproductiv e system and breast disorders	Testicular appendage torsion	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Ear and labyrinth disorders			4.2% (1.7, 10.1)	1.2% (0.2, 8.2)	P=0.170 , I <sup>2</sup> =47%	P=0.970 , I <sup>2</sup> =0%							P=0.374
Ear and labyrinth disorders		Mild	4.2% (1.7, 10.1)	1.2% (0.2, 8.2)	P=0.170 , I <sup>2</sup> =47%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.027 (0.001 - 0.054)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=0.374
Ear and labyrinth disorders		Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Ear and labyrinth disorders		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Ear and labyrinth disorders	Ear pain		4.2% (1.7, 10.1)	1.2% (0.2, 8.2)	P=0.170, I <sup>2</sup> =47%	P=0.970, I <sup>2</sup> =0%							P=0.433
Ear and labyrinth disorders	Ear pain	Mild	4.2% (1.7, 10.1)	1.2% (0.2, 8.2)	P=0.170, I <sup>2</sup> =47%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.027 (0.001 - 0.054)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.433
Ear and labyrinth disorders	Ear pain	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Ear and labyrinth disorders	Ear pain	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Ear and labyrinth disorders	Cerumen impaction		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.717
Ear and labyrinth disorders	Cerumen impaction	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.717
Ear and labyrinth disorders	Cerumen impaction	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Ear and labyrinth disorders	Cerumen impaction	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Ear and labyrinth disorders	Motion sickness		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Ear and labyrinth disorders	Motion sickness	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.732
Ear and labyrinth disorders	Motion sickness	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Ear and labyrinth disorders	Motion sickness	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Psychiatric disorders			2.0% (0.6, 6.7)	2.0% (0.4, 9.2)	P=0.395 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%							P=0.756

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Psychiatric disorders		Mild	1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	0.533 (0.032 - 8.755)	0.539 (0.035 - 8.402)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.548
Psychiatric disorders		Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Psychiatric disorders		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Psychiatric disorders	Attention deficit/hyperactivity disorder		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.461
Psychiatric disorders	Attention deficit/hyperactivity disorder	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.461

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Psychiatric disorders	Attention deficit/hyper activity disorder	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Psychiatric disorders	Attention deficit/hyper activity disorder	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Psychiatric disorders	Affect lability		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.718
Psychiatric disorders	Affect lability	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Psychiatric disorders	Affect lability	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Psychiatric disorders	Affect lability	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Psychiatric disorders	Depressive symptom		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Psychiatric disorders	Depressive symptom	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Psychiatric disorders	Depressive symptom	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Psychiatric disorders	Depressive symptom	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Psychiatric disorders	Enuresis		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Psychiatric disorders	Enuresis	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Psychiatric disorders	Enuresis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Psychiatric disorders	Enuresis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Cardiac disorders			2.1% (0.7, 6.4)	1.2% (0.2, 8.2)	P=0.606, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.665
Cardiac disorders		Mild	1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.729, I <sup>2</sup> =0%	P=0.788
Cardiac disorders		Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Cardiac disorders		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Cardiac disorders	Sinoatrial block		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Cardiac disorders	Sinoatrial block	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Cardiac disorders	Sinoatrial block	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Cardiac disorders	Sinoatrial block	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Cardiac disorders	Sinus tachycardia		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Cardiac disorders	Sinus tachycardia	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Cardiac disorders	Sinus tachycardia	Moderate	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Cardiac disorders	Sinus tachycardia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Cardiac disorders	Tachycardia		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Cardiac disorders	Tachycardia	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Cardiac disorders	Tachycardia	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Cardiac disorders	Tachycardia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Cardiac disorders	Wandering pacemaker		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Cardiac disorders	Wandering pacemaker	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Cardiac disorders	Wandering pacemaker	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Cardiac disorders	Wandering pacemaker	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Cardiac disorders	Myocarditis		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Cardiac disorders	Myocarditis	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Cardiac disorders	Myocarditis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Cardiac disorders	Myocarditis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%							P=0.548

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Mild	1.1% (0.2, 5.1)	2.0% (0.4, 9.2)	P=0.711, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	0.533 (0.032 - 8.755)	0.539 (0.035 - 8.402)	-0.006 (-0.034 - 0.022)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.548
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.342

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973 , I <sup>2</sup> =0%	P=0.708 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.342
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Renal and urinary disorders			1.1% (0.2, 5.1)	2.0% (0.4, 9.4)	P=0.711 , I <sup>2</sup> =0%	P=0.644 , I <sup>2</sup> =0%							P=0.704
Renal and urinary disorders		Mild	1.1% (0.2, 5.1)	2.0% (0.4, 9.4)	P=0.711 , I <sup>2</sup> =0%	P=0.644 , I <sup>2</sup> =0%	0.538 (0.034 - 8.575)	0.538 (0.034 - 8.554)	-0.006 (-0.034 - 0.022)	P=0.335, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	P=0.324, I <sup>2</sup> =0%	P=0.704

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Renal and urinary disorders		Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Renal and urinary disorders		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Renal and urinary disorders	Polyuria		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718
Renal and urinary disorders	Polyuria	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Renal and urinary disorders	Polyuria	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Renal and urinary disorders	Polyuria	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Renal and urinary disorders	Pollakiuria		0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Renal and urinary disorders	Pollakiuria	Mild	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.732
Renal and urinary disorders	Pollakiuria	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Renal and urinary disorders	Pollakiuria	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Renal and urinary disorders	Nocturia		0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%							P=0.732
Renal and urinary disorders	Nocturia	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.4)	P=0.973, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732
Renal and urinary disorders	Nocturia	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Renal and urinary disorders	Nocturia	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Vascular disorders			1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.788
Vascular disorders		Mild	1.4% (0.3, 5.3)	1.2% (0.2, 8.2)	P=0.961, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.729, I <sup>2</sup> =0%	P=0.788
Vascular disorders		Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Vascular disorders		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Vascular disorders	Hypotension		1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Vascular disorders	Hypotension	Mild	1.1% (0.2, 5.1)	1.2% (0.2, 8.2)	P=0.711, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.992
Vascular disorders	Hypotension	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Vascular disorders	Hypotension	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Vascular disorders	Cyanosis		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Vascular disorders	Cyanosis	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Vascular disorders	Cyanosis	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Vascular disorders	Cyanosis	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Congenital, familial and genetic disorders			2.1% (0.6, 7.0)	1.2% (0.2, 8.2)	P=0.349, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.579

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Congenital, familial and genetic disorders		Mild	2.1% (0.6, 7.0)	1.2% (0.2, 8.2)	P=0.349 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.579
Congenital, familial and genetic disorders		Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Congenital, familial and genetic disorders		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Congenital, familial and genetic disorders	Buried penis syndrome		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.718



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Congenital, familial and genetic disorders	Buried penis syndrome	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Congenital, familial and genetic disorders	Buried penis syndrome	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Congenital, familial and genetic disorders	Buried penis syndrome	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.992
Congenital, familial and genetic disorders	Supernumerary teeth		1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653 , I <sup>2</sup> =0%	P=0.970 , I <sup>2</sup> =0%							P=0.718

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Congenital, familial and genetic disorders	Supernumerary teeth	Mild	1.1% (0.2, 5.2)	1.2% (0.2, 8.2)	P=0.653, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.006 - 0.020)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.718
Congenital, familial and genetic disorders	Supernumerary teeth	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Congenital, familial and genetic disorders	Supernumerary teeth	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Hepatobiliary disorders			0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.733

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Hepatobiliary disorders		Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.733
Hepatobiliary disorders		Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Hepatobiliary disorders		Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Hepatobiliary disorders	Hepatomegaly		0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%							P=0.733

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL													
Hepatobiliary disorders	Hepatomegaly	Mild	0.7% (0.1, 4.6)	2.0% (0.4, 9.2)	P=0.973, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.733
Hepatobiliary disorders	Hepatomegaly	Moderate	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992
Hepatobiliary disorders	Hepatomegaly	Severe	0.7% (0.1, 4.6)	1.2% (0.2, 8.2)	P=0.973, I <sup>2</sup> =0%	P=0.970, I <sup>2</sup> =0%							P=0.992

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Any adverse event			77.0% (60.5, 88.0)	70.4% (48.6, 85.6)	P=0.036, I <sup>2</sup> =77.2%	P=0.054, I <sup>2</sup> =73%							
Any adverse event		Mild	59.2% (43.0, 73.6)	54.4% (34.5, 73.0)	P=0.001, I <sup>2</sup> =91.4%	P=0.014, I <sup>2</sup> =83%	2.029 (0.693 - 5.940)	1.217 (0.887 - 1.669)	0.123 (-0.063 - 0.309)	P=0.536, I <sup>2</sup> =0%	P=0.688, I <sup>2</sup> =0%	P=0.930, I <sup>2</sup> =0%	
Any adverse event		Moderate	21.4% (11.3, 36.6)	20.9% (9.6, 39.6)	P=0.031, I <sup>2</sup> =78.4%	P=0.369, I <sup>2</sup> =0%	0.721 (0.221 - 2.350)	0.776 (0.313 - 1.921)	-0.045 (-0.211 - 0.121)	P=0.301, I <sup>2</sup> =639%	P=0.280, I <sup>2</sup> =1417%	P=0.490, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Any adverse event		Severe	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations			51.7% (39.0, 64.2)	69.0% (49.9, 83.2)	P=1.000, I <sup>2</sup> =0%	P=0.239, I <sup>2</sup> =28%							
Infections and infestations		Mild	44.9% (32.6, 57.7)	55.7% (36.9, 73.1)	P=0.598, I <sup>2</sup> =0%	P=0.072, I <sup>2</sup> =69%	0.614 (0.250 - 1.511)	0.791 (0.521 - 1.202)	-0.118 (-0.335 - 0.098)	P=0.230, I <sup>2</sup> =305%	P=0.309, I <sup>2</sup> =339%	P=0.217, I <sup>2</sup> =344%	
Infections and infestations		Moderate	7.9% (2.8, 20.5)	15.0% (5.7, 34.0)	P=0.216, I <sup>2</sup> =34.6%	P=0.304, I <sup>2</sup> =5%	0.336 (0.066 - 1.704)	0.388 (0.096 - 1.567)	-0.082 (-0.213 - 0.050)	P=0.575, I <sup>2</sup> =0%	P=0.536, I <sup>2</sup> =0%	P=0.889, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations		Severe	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Upper respiratory tract infection		30.2% (19.1, 44.2)	49.1% (27.2, 71.4)	P=0.024, I <sup>2</sup> =80.4%	P=0.004, I <sup>2</sup> =88%							
Infections and infestations	Upper respiratory tract infection	Mild	30.2% (19.1, 44.2)	48.8% (26.5, 71.5)	P=0.024, I <sup>2</sup> =80.4%	P=0.012, I <sup>2</sup> =84%	0.863 (0.291 - 2.554)	0.920 (0.498 - 1.697)	-0.024 (-0.203 - 0.155)	P=0.126, I <sup>2</sup> =5729%	P=0.141, I <sup>2</sup> =5394%	P=0.036, I <sup>2</sup> =7728%	
Infections and infestations	Upper respiratory tract infection	Moderate	1.7% (0.2, 10.9)	6.7% (1.7, 23.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.067 (-0.156 - 0.023)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.847, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Infections and infestations	Upper respiratory tract infection	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Nasopharyngitis		5.5% (1.8, 15.6)	16.9% (7.2, 34.8)	P=0.561, I <sup>2</sup> =0%	P=0.626, I <sup>2</sup> =0%							
Infections and infestations	Nasopharyngitis	Mild	5.5% (1.8, 15.6)	15.0% (5.7, 34.0)	P=0.561, I <sup>2</sup> =0%	P=0.304, I <sup>2</sup> =5%	0.349 (0.072 - 1.691)	0.388 (0.094 - 1.604)	-0.082 (-0.215 - 0.052)	P=0.765, I <sup>2</sup> =0%	P=0.803, I <sup>2</sup> =0%	P=0.420, I <sup>2</sup> =0%	
Infections and infestations	Nasopharyngitis	Moderate	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Infections and infestations	Nasopharyngitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis		5.5% (1.8, 15.6)	9.9% (2.8, 29.0)	P=0.561, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis	Mild	5.5% (1.8, 15.6)	9.9% (2.8, 29.0)	P=0.561, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	0.759 (0.118 - 4.894)	0.776 (0.140 - 4.312)	-0.015 (-0.120 - 0.090)	P=0.528, I <sup>2</sup> =0%	P=0.534, I <sup>2</sup> =0%	P=0.449, I <sup>2</sup> =0%	
Infections and infestations	Pharyngitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Respiratory tract infection		5.5% (1.8, 15.6)	9.9% (2.8, 29.0)	P=0.561, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection	Mild	5.5% (1.8, 15.6)	9.9% (2.8, 29.0)	P=0.561, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	0.768 (0.124 - 4.762)	0.776 (0.134 - 4.477)	-0.015 (-0.122 - 0.092)	P=0.211, I <sup>2</sup> =360%	P=0.217, I <sup>2</sup> =344%	P=0.179, I <sup>2</sup> =446%	
Infections and infestations	Respiratory tract infection	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Bronchitis		5.5% (1.8, 15.6)	5.2% (1.0, 22.0)	P=0.561, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Infections and infestations	Bronchitis	Mild	3.4% (0.9, 12.8)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.034 (-0.012 - 0.081)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.706, I <sup>2</sup> =0%	
Infections and infestations	Bronchitis	Moderate	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Bronchitis	Severe	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Tonsillitis		5.5% (1.8, 15.6)	9.9% (2.8, 29.0)	P=0.561, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis	Mild	5.5% (1.8, 15.6)	9.9% (2.8, 29.0)	P=0.561, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	0.759 (0.118 - 4.894)	0.776 (0.140 - 4.312)	-0.015 (-0.120 - 0.090)	P=0.528, I <sup>2</sup> =0%	P=0.534, I <sup>2</sup> =0%	P=0.449, I <sup>2</sup> =0%	
Infections and infestations	Tonsillitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis		1.7% (0.2, 10.9)	9.9% (2.8, 29.0)	P=1.000, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Infections and infestations	Gastroenteritis	Mild	1.7% (0.2, 10.9)	9.9% (2.8, 29.0)	P=1.000, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.067 (-0.156 - 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Gastroenteritis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rhinitis		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Infections and infestations	Rhinitis	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Rhinitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rhinitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngitis streptococcal		1.7% (0.2, 10.9)	20.5% (8.2, 42.7)	P=1.000, I <sup>2</sup> =0%	P=0.118, I <sup>2</sup> =59%							
Infections and infestations	Pharyngitis streptococcal	Mild	1.7% (0.2, 10.9)	9.9% (2.8, 29.0)	P=1.000, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.067 (-0.156 - 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Infections and infestations	Pharyngitis streptococcal	Moderate	1.7% (0.2, 10.9)	9.9% (2.8, 29.0)	P=1.000, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.067 (-0.156 - 0.023)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Pharyngitis streptococcal	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pneumonia		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Infections and infestations	Pneumonia	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Infections and infestations	Pneumonia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pneumonia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinusitis		5.5% (1.8, 15.6)	5.2% (1.0, 22.0)	P=0.561, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Infections and infestations	Sinusitis	Mild	3.4% (0.9, 12.8)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	1.036 (0.090 - 11.909)	1.034 (0.098 - 10.952)	0.001 (-0.078 - 0.081)	P=0.568, I <sup>2</sup> =0%	P=0.567, I <sup>2</sup> =0%	P=0.585, I <sup>2</sup> =0%	
Infections and infestations	Sinusitis	Moderate	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Sinusitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral infection		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral infection	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral infection	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral infection	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Ear infection		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Ear infection	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Ear infection	Moderate	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Ear infection	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Respiratory tract infection viral		2.7% (0.5, 12.3)	5.2% (1.0, 22.0)	P=0.671, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection viral	Mild	2.7% (0.5, 12.3)	5.2% (1.0, 22.0)	P=0.671, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	0.500 (0.029 - 8.602)	0.517 (0.035 - 7.703)	-0.016 (-0.088 - 0.056)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Respiratory tract infection viral	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Respiratory tract infection viral	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Gastroenteritis viral		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis viral	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis viral	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastroenteritis viral	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis media acute		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Infections and infestations	Otitis media acute	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Otitis media acute	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis media acute	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis		2.7% (0.5, 12.3)	5.2% (1.0, 22.0)	P=0.671, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Infections and infestations	Conjunctivitis	Mild	2.7% (0.5, 12.3)	5.2% (1.0, 22.0)	P=0.671, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	0.517 (0.032 - 8.269)	0.517 (0.032 - 8.269)	-0.016 (-0.089 - 0.057)	P=0.329, I <sup>2</sup> =0%	P=0.332, I <sup>2</sup> =0%	P=0.321, I <sup>2</sup> =0%	
Infections and infestations	Conjunctivitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Varicella		5.2% (1.5, 16.3)	3.1% (0.4, 19.1)	P=0.358, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Varicella	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Infections and infestations	Varicella	Moderate	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Varicella	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Enteritis infectious		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Enteritis infectious	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Enteritis infectious	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Enteritis infectious	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Influenza		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Influenza	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Influenza	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Influenza	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Enterobiasis		2.7% (0.5, 12.3)	5.2% (1.0, 22.0)	P=0.671, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Infections and infestations	Enterobiasis	Mild	2.7% (0.5, 12.3)	5.2% (1.0, 22.0)	P=0.671, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	0.500 (0.029 - 8.602)	0.517 (0.035 - 7.703)	-0.016 (-0.088 - 0.056)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Enterobiasis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Enterobiasis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Herpangina		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Herpangina	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Herpangina	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Herpangina	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis media		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Infections and infestations	Otitis media	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis media	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis media	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Periodontitis		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Periodontitis	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Periodontitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Periodontitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Helminthic infection		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Helminthic infection	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Helminthic infection	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Helminthic infection	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngoton sillitis		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngoton sillitis	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngoton sillitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pharyngoton sillitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Viral upper respiratory tract infection		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral upper respiratory tract infection	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral upper respiratory tract infection	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Viral upper respiratory tract infection	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Hordeolum		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hordeolum	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hordeolum	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hordeolum	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pulpitis dental		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Pulpitis dental	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pulpitis dental	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Pulpitis dental	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Urinary tract infection		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Infections and infestations	Urinary tract infection	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Urinary tract infection	Moderate	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Urinary tract infection	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Laryngitis		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Laryngitis	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Laryngitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Laryngitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Oral herpes		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Oral herpes	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Oral herpes	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Infections and infestations	Oral herpes	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hand-foot-and-mouth disease		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hand-foot-and-mouth disease	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Hand-foot-and-mouth disease	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Hand-foot-and-mouth disease	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Appendicitis		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Appendicitis	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Appendicitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Appendicitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Atypical pneumonia		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Atypical pneumonia	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Atypical pneumonia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Atypical pneumonia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis bacterial		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis bacterial	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Conjunctivitis bacterial	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Conjunctivitis bacterial	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Croup infectious		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Croup infectious	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Croup infectious	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Croup infectious	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Cystitis		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Cystitis	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Cystitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Cystitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Eczema infected		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Eczema infected	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Eczema infected	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Eczema infected	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Infected bite		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Infected bite	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Infected bite	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Infected bite	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Laryngitis viral		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Laryngitis viral	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Laryngitis viral	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Laryngitis viral	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis externa		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis externa	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Otitis externa	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Otitis externa	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rotavirus infection		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rotavirus infection	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rotavirus infection	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Rotavirus infection	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Vulvitis		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Vulvitis	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Vulvitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Vulvitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Molluscum contagiosum		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Molluscum contagiosum	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Molluscum contagiosum	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Molluscum contagiosum	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tinea pedis		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

			Lonapegsomatropin vs. Daily somatropin										
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Infections and infestations	Tinea pedis	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Tinea pedis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tinea pedis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tooth abscess		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tooth abscess	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Tooth abscess	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tooth abscess	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Abscess limb		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Abscess limb	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Abscess limb	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Abscess limb	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Bacterial infection		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Bacterial infection	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Bacterial infection	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Bacterial infection	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Chronic sinusitis		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Chronic sinusitis	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Chronic sinusitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Chronic sinusitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Chronic tonsillitis		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Chronic tonsillitis	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Chronic tonsillitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Chronic tonsillitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Folliculitis		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Folliculitis	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Folliculitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Folliculitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Herpes virus infection		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Herpes virus infection	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Herpes virus infection	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Herpes virus infection	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Infectious mononucleosis		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Infectious mononucleosis	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Infectious mononucleosis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Infectious mononucleosis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Sinobronchitis		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinobronchitis	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinobronchitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Sinobronchitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Subcutaneous abscess		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Subcutaneous abscess	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Subcutaneous abscess	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Subcutaneous abscess	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis bacterial		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis bacterial	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Tonsillitis bacterial	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tonsillitis bacterial	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tracheitis		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tracheitis	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Tracheitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Infections and infestations	Tracheitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastrointestinal bacterial infection		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastrointestinal bacterial infection	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Gastrointestinal bacterial infection	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Gastrointestinal bacterial infection	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Mumps		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Mumps	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Mumps	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Mumps	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Myringitis		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Myringitis	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Myringitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Myringitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Peritonsillar abscess		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Infections and infestations	Peritonsillar abscess	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Infections and infestations	Peritonsillar abscess	Moderate	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Infections and infestations	Peritonsillar abscess	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations			40.8% (26.4, 57.0)	37.5% (18.7, 60.9)	P=0.001, I <sup>2</sup> =91.4%	P=0.031, I <sup>2</sup> =79%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigations		Mild	40.8% (26.4, 57.0)	37.5% (18.7, 60.9)	P=0.001, I <sup>2</sup> =91.4%	P=0.031, I <sup>2</sup> =79%	1.736 (0.523 - 5.764)	1.330 (0.697 - 2.537)	0.077 (-0.085 - 0.239)	P=0.653, I <sup>2</sup> =0%	P=0.558, I <sup>2</sup> =0%	P=0.706, I <sup>2</sup> =0%	
Investigations		Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood glucose increased		16.8% (7.9, 32.2)	26.1% (11.5, 49.1)	P=0.068, I <sup>2</sup> =70%	P=0.075, I <sup>2</sup> =69%							
Investigations	Blood glucose increased	Mild	16.8% (7.9, 32.2)	26.1% (11.5, 49.1)	P=0.068, I <sup>2</sup> =70%	P=0.075, I <sup>2</sup> =69%	0.522 (0.129 - 2.116)	0.621 (0.226 - 1.704)	-0.063 (-0.207 - 0.080)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigation s	Blood glucose increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigation s	Blood glucose increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigation s	Insulin-like growth factor increased		23.0% (12.0, 39.5)	3.1% (0.4, 19.1)	P=0.036, I <sup>2</sup> =77.2%	P=1.000, I <sup>2</sup> =0%							
Investigation s	Insulin-like growth factor increased	Mild	23.0% (12.0, 39.5)	3.1% (0.4, 19.1)	P=0.036, I <sup>2</sup> =77.2%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.138 (0.049 - 0.227)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigations	Insulin-like growth factor increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Insulin-like growth factor increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Low density lipoprotein increased		5.2% (1.5, 16.3)	9.9% (2.8, 29.0)	P=0.358, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%							
Investigations	Low density lipoprotein increased	Mild	5.2% (1.5, 16.3)	9.9% (2.8, 29.0)	P=0.358, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	0.481 (0.061 - 3.810)	0.517 (0.081 - 3.317)	-0.032 (-0.131 - 0.066)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Investigation s	Low density lipoprotein increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigation s	Low density lipoprotein increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigation s	Blood alkaline phosphatase increased		5.2% (1.5, 16.3)	5.2% (1.0, 22.0)	P=0.358, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Investigation s	Blood alkaline phosphatase increased	Mild	5.2% (1.5, 16.3)	5.2% (1.0, 22.0)	P=0.358, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	1.037 (0.086 - 12.455)	1.034 (0.102 - 10.507)	0.001 (-0.077 - 0.079)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigations	Blood alkaline phosphatase increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood alkaline phosphatase increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Eosinophil count increased		5.5% (1.8, 15.6)	3.1% (0.4, 19.1)	P=0.561, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Eosinophil count increased	Mild	5.5% (1.8, 15.6)	3.1% (0.4, 19.1)	P=0.561, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.052 (-0.005 - 0.109)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.576, I <sup>2</sup> =0%	



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigation s	Eosinophil count increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigation s	Eosinophil count increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigation s	Alanine aminotransfe rase increased		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Investigation s	Alanine aminotransfe rase increased	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Investigations	Alanine aminotransferase increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Alanine aminotransferase increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron increased		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Investigations	Blood iron increased	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood iron increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigations	Blood iron increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood uric acid increased		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood uric acid increased	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood uric acid increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood uric acid increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Investigations	Blood phosphorus increased		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood phosphorus increased	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood phosphorus increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood phosphorus increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol decreased		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigations	Cortisol decreased	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Cortisol decreased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol decreased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Aspartate aminotransferase increased		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Investigations	Aspartate aminotransferase increased	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Aspartate aminotransferase increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Aspartate aminotransferase increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood triglycerides increased		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood triglycerides increased	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Investigation s	Blood triglycerides increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigation s	Blood triglycerides increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigation s	Blood glucose abnormal		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigation s	Blood glucose abnormal	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigation s	Blood glucose abnormal	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigations	Blood glucose abnormal	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood thyroid stimulating hormone increased		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood thyroid stimulating hormone increased	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Investigation s	Blood thyroid stimulating hormone increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Blood thyroid stimulating hormone increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	White blood cell count decreased		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	White blood cell count decreased	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigation s	White blood cell count decreased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	White blood cell count decreased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Tri-iodothyronine free increased		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Tri-iodothyronine free increased	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Investigations	Tri-iodothyronine free increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Tri-iodothyronine free increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood urea increased		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Investigations	Blood urea increased	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood urea increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Investigations	Blood urea increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram T wave peaked		5.2% (1.5, 16.3)	3.1% (0.4, 19.1)	P=0.358, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram T wave peaked	Mild	5.2% (1.5, 16.3)	3.1% (0.4, 19.1)	P=0.358, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.034 (-0.012 - 0.081)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Electrocardiogram T wave peaked	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigations	Electrocardiogram T wave peaked	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cortisol decreased		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cortisol decreased	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cortisol decreased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cortisol decreased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigations	Blood iron decreased		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron decreased	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron decreased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood iron decreased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol free urine decreased		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Investigations	Cortisol free urine decreased	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol free urine decreased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Cortisol free urine decreased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine decreased		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine decreased	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigations	Thyroxine decreased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine decreased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Transaminases increased		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Transaminases increased	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Transaminases increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigations	Transaminases increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood cholesterol increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Investigations	Electrocardiogram ST segment abnormal		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram ST segment abnormal	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram ST segment abnormal	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram ST segment abnormal	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Haemoglobin decreased		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigations	Haemoglobin decreased	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Haemoglobin decreased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Haemoglobin decreased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme abnormal		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme abnormal	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigations	Hepatic enzyme abnormal	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme abnormal	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme increased		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme increased	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Hepatic enzyme increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigations	Hepatic enzyme increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Lipids increased		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Lipids increased	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Lipids increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Lipids increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigation s	Liver function test abnormal		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Liver function test abnormal	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Liver function test abnormal	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Investigation s	Liver function test abnormal	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigations	Thyroid function test abnormal		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroid function test abnormal	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroid function test abnormal	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroid function test abnormal	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigations	Thyroxine free decreased		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine free decreased	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine free decreased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Thyroxine free decreased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Basophil count increased		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigations	Basophil count increased	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Basophil count increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Basophil count increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood lactate dehydrogenase increased		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Investigations	Blood lactate dehydrogenase increased	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood lactate dehydrogenase increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood lactate dehydrogenase increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood potassium increased		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Investigations	Blood potassium increased	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood potassium increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood potassium increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood pressure increased		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Investigations	Blood pressure increased	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Investigations	Blood pressure increased	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Blood pressure increased	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram high voltage		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram high voltage	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Investigations	Electrocardiogram high voltage	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Investigations	Electrocardiogram high voltage	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders			31.1% (20.6, 44.1)	33.7% (19.1, 52.2)	P=0.571, I <sup>2</sup> =0%	P=0.441, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders		Mild	29.6% (19.2, 42.6)	20.9% (9.6, 39.6)	P=0.389, I <sup>2</sup> =0%	P=0.369, I <sup>2</sup> =0%	1.675 (0.575 - 4.879)	1.466 (0.650 - 3.303)	0.093 (-0.090 - 0.276)	P=0.750, I <sup>2</sup> =0%	P=0.703, I <sup>2</sup> =0%	P=0.870, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Respiratory, thoracic and mediastinal disorders		Moderate	2.7% (0.5, 12.3)	13.3% (5.1, 30.6)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	0.114 (0.012 - 1.086)	0.129 (0.015 - 1.106)	-0.116 (-0.242 - 0.010)	P=0.564, I <sup>2</sup> =0%	P=0.549, I <sup>2</sup> =0%	P=0.756, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Cough		17.9% (9.5, 31.2)	31.0% (16.8, 50.1)	P=0.087, I <sup>2</sup> =65.9%	P=0.239, I <sup>2</sup> =28%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Cough	Mild	17.9% (9.5, 31.2)	20.9% (9.6, 39.6)	P=0.087, I <sup>2</sup> =65.9%	P=0.369, I <sup>2</sup> =0%	0.725 (0.226 - 2.333)	0.776 (0.311 - 1.937)	-0.045 (-0.212 - 0.123)	P=0.641, I <sup>2</sup> =0%	P=0.607, I <sup>2</sup> =0%	P=0.809, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Cough	Moderate	1.7% (0.2, 10.9)	10.5% (3.4, 28.1)	P=1.000, I <sup>2</sup> =0%	P=0.550, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.100 (-0.207 - 0.007)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.605, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Cough	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea		5.2% (1.5, 16.3)	9.9% (2.8, 29.0)	P=0.358, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Mild	5.2% (1.5, 16.3)	9.9% (2.8, 29.0)	P=0.358, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	0.481 (0.061 - 3.810)	0.517 (0.081 - 3.317)	-0.032 (-0.131 - 0.066)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic		3.4% (0.9, 12.8)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Mild	3.4% (0.9, 12.8)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	1.036 (0.090 - 11.909)	1.034 (0.098 - 10.952)	0.001 (-0.078 - 0.081)	P=0.568, I <sup>2</sup> =0%	P=0.567, I <sup>2</sup> =0%	P=0.585, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Asthma		5.2% (1.5, 16.3)	6.7% (1.7, 23.1)	P=0.358, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Asthma	Mild	2.7% (0.5, 12.3)	5.2% (1.0, 22.0)	P=0.671, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	0.517 (0.032 - 8.269)	0.517 (0.032 - 8.269)	-0.016 (-0.089 - 0.057)	P=0.329, I <sup>2</sup> =0%	P=0.332, I <sup>2</sup> =0%	P=0.321, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Asthma	Moderate	2.7% (0.5, 12.3)	5.2% (1.0, 22.0)	P=0.671, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	0.500 (0.029 - 8.602)	0.517 (0.035 - 7.703)	-0.016 (-0.088 - 0.056)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Asthma	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Respiratory disorder		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Moderate	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Epistaxis		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Epistaxis	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Epistaxis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Epistaxis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal congestion		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Wheezing		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Wheezing	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Wheezing	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Wheezing	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sinus congestion		5.2% (1.5, 16.3)	3.1% (0.4, 19.1)	P=0.358, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Mild	5.2% (1.5, 16.3)	3.1% (0.4, 19.1)	P=0.358, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.034 (-0.012 - 0.081)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Allergic cough		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Allergic cough	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Allergic cough	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Allergic cough	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Laryngospasm		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Nasal obstruction		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Productive cough		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Productive cough	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Respiratory, thoracic and mediastinal disorders	Productive cough	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Respiratory, thoracic and mediastinal disorders	Productive cough	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders			18.4% (10.2, 31.1)	20.0% (9.3, 37.9)	P=0.175, I <sup>2</sup> =45.6%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Gastrointestinal disorders		Mild	18.4% (10.2, 31.1)	16.9% (7.2, 34.8)	P=0.175, I <sup>2</sup> =45.6%	P=0.626, I <sup>2</sup> =0%	1.041 (0.324 - 3.346)	1.034 (0.386 - 2.775)	0.006 (-0.161 - 0.172)	P=0.228, I <sup>2</sup> =3127%	P=0.232, I <sup>2</sup> =2996%	P=0.220, I <sup>2</sup> =3339%	
Gastrointestinal disorders		Moderate	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Diarrhoea		5.5% (1.8, 15.6)	10.5% (3.4, 28.1)	P=0.561, I <sup>2</sup> =0%	P=0.550, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Gastrointestinal disorders	Diarrhoea	Mild	5.5% (1.8, 15.6)	10.5% (3.4, 28.1)	P=0.561, I <sup>2</sup> =0%	P=0.550, I <sup>2</sup> =0%	0.494 (0.094 - 2.592)	0.517 (0.110 - 2.426)	-0.048 (-0.170 - 0.074)	P=0.404, I <sup>2</sup> =0%	P=0.407, I <sup>2</sup> =0%	P=0.406, I <sup>2</sup> =0%	
Gastrointestinal disorders	Diarrhoea	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Diarrhoea	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Vomiting		3.4% (0.9, 12.8)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Gastrointestinal disorders	Vomiting	Mild	3.4% (0.9, 12.8)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	1.036 (0.090 - 11.909)	1.034 (0.098 - 10.952)	0.001 (-0.078 - 0.081)	P=0.568, I <sup>2</sup> =0%	P=0.567, I <sup>2</sup> =0%	P=0.585, I <sup>2</sup> =0%	



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Gastrointestinal disorders	Vomiting	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Vomiting	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Nausea		3.4% (0.9, 12.8)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Gastrointestinal disorders	Nausea	Mild	3.4% (0.9, 12.8)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.034 (-0.012 - 0.081)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.706, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Gastrointesti nal disorders	Nausea	Moderate	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Gastrointesti nal disorders	Nausea	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Abdominal pain		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Abdominal pain	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Gastrointesti nal disorders	Abdominal pain	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Gastrointestinal disorders	Abdominal pain	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal pain upper		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal pain upper	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Abdominal pain upper	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal pain upper	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Gastrointestinal disorders	Dyspepsia		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Dyspepsia	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Dyspepsia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Dyspepsia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Gastrointestinal disorders	Constipation		5.2% (1.5, 16.3)	3.1% (0.4, 19.1)	P=0.358, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Constipation	Mild	5.2% (1.5, 16.3)	3.1% (0.4, 19.1)	P=0.358, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.034 (-0.012 - 0.081)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Constipation	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Constipation	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Toothache		2.7% (0.5, 12.3)	5.2% (1.0, 22.0)	P=0.671, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Gastrointesti nal disorders	Toothache	Mild	2.7% (0.5, 12.3)	5.2% (1.0, 22.0)	P=0.671 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%	0.500 (0.029 - 8.602)	0.517 (0.035 - 7.703)	-0.016 (-0.088 - 0.056)	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	P=1.00 0, I <sup>2</sup> =0%	
Gastrointesti nal disorders	Toothache	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Toothache	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Abdominal discomfort		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Gastrointestinal disorders	Abdominal discomfort	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Gastrointestinal disorders	Abdominal discomfort	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Abdominal discomfort	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Enteritis		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Enteritis	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Gastrointesti nal disorders	Enteritis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Enteritis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastrointesti nal disorder		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastrointesti nal disorder	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
Gastrointesti nal disorders	Gastrointesti nal disorder	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Gastrointesti nal disorders	Gastrointesti nal disorder	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Aphthous ulcer		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Aphthous ulcer	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Aphthous ulcer	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Aphthous ulcer	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Gastrointesti nal disorders	Gastric disorder		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastric disorder	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastric disorder	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastric disorder	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastrointesti nal motility disorder		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Gastrointesti nal disorders	Gastrointesti nal motility disorder	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastrointesti nal motility disorder	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Gastrointesti nal motility disorder	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Lip swelling		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Lip swelling	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Gastrointesti nal disorders	Lip swelling	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Lip swelling	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Abdominal distension		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Abdominal distension	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Gastrointesti nal disorders	Abdominal distension	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Gastrointestinal disorders	Abdominal distension	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Noninfective gingivitis		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Noninfective gingivitis	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Noninfective gingivitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Gastrointestinal disorders	Noninfective gingivitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administration site conditions			15.5% (7.9, 28.2)	20.0% (9.3, 37.9)	P=0.145, I <sup>2</sup> =52.9%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions		Mild	13.0% (5.9, 26.2)	16.9% (7.2, 34.8)	P=0.119, I <sup>2</sup> =58.9%	P=0.626, I <sup>2</sup> =0%	0.583 (0.164 - 2.078)	0.621 (0.204 - 1.890)	-0.063 (-0.219 - 0.093)	P=0.135, I <sup>2</sup> =5514%	P=0.135, I <sup>2</sup> =5518%	P=0.190, I <sup>2</sup> =4168%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administrati on site conditions		Moderate	3.4% (0.9, 12.8)	5.2% (1.0, 22.0)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%	1.036 (0.090 - 11.909)	1.034 (0.098 - 10.952)	0.001 (-0.078 - 0.081)	P=0.568, I <sup>2</sup> =0%	P=0.567, I <sup>2</sup> =0%	P=0.585, I <sup>2</sup> =0%	
General disorders and administrati on site conditions		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Pyrexia		13.1% (6.4, 25.2)	13.3% (5.1, 30.6)	P=0.241 , I <sup>2</sup> =27.2 %	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administrati on site conditions	Pyrexia	Mild	10.3% (4.3, 22.7)	10.5% (3.4, 28.1)	P=0.193 , I <sup>2</sup> =41%	P=0.550 , I <sup>2</sup> =0%	0.852 (0.192 - 3.780)	0.862 (0.218 - 3.413)	-0.014 (-0.144 - 0.117)	P=0.188, I <sup>2</sup> =423 5%	P=0.192, I <sup>2</sup> =412 9%	P=0.193, I <sup>2</sup> =409 8%	
General disorders and administrati on site conditions	Pyrexia	Moderate	3.4% (0.9, 12.8)	5.2% (1.0, 22.0)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%	1.036 (0.090 - 11.909)	1.034 (0.098 - 10.952)	0.001 (-0.078 - 0.081)	P=0.568, I <sup>2</sup> =0%	P=0.567, I <sup>2</sup> =0%	P=0.585, I <sup>2</sup> =0%	



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administrati on site conditions	Pyrexia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site pain		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site pain	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administration site conditions	Injection site pain	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site pain	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administrati on site conditions	Injection site pruritus		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site pruritus	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site pruritus	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administration site conditions	Injection site pruritus	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Fatigue		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administrati on site conditions	Fatigue	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Fatigue	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Fatigue	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administrati on site conditions	Injection site swelling		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site swelling	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
General disorders and administration site conditions	Injection site swelling	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site swelling	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site erythema		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
General disorders and administrati on site conditions	Injection site erythema	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
General disorders and administrati on site conditions	Injection site erythema	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
General disorders and administration site conditions	Injection site erythema	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site reaction		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Injection site reaction	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
General disorders and administrati on site conditions	Injection site reaction	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site reaction	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administrati on site conditions	Face oedema		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Face oedema	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Face oedema	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administration site conditions	Face oedema	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Gait disturbance		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administrati on site conditions	Gait disturbance	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Gait disturbance	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Gait disturbance	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administrati on site conditions	Influenza like illness		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Influenza like illness	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administrati on site conditions	Influenza like illness	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Influenza like illness	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site atrophy		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
General disorders and administrati on site conditions	Injection site atrophy	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site atrophy	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
General disorders and administrati on site conditions	Injection site atrophy	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site urticaria		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site urticaria	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
General disorders and administrati on site conditions	Injection site urticaria	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site urticaria	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administrati on site conditions	Medical device discomfort		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Medical device discomfort	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Medical device discomfort	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
General disorders and administrati on site conditions	Medical device discomfort	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Vaccination site pain		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
General disorders and administrati on site conditions	Vaccination site pain	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Vaccination site pain	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Vaccination site pain	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administrati on site conditions	Injection site bruising		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site bruising	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administrati on site conditions	Injection site bruising	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site bruising	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Pain		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administrati on site conditions	Pain	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Pain	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administrati on site conditions	Pain	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Peripheral swelling		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Peripheral swelling	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administration site conditions	Peripheral swelling	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
General disorders and administration site conditions	Peripheral swelling	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administrati on site conditions	Injection site haemorrhage		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%							
General disorders and administrati on site conditions	Injection site haemorrhage	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000 , I <sup>2</sup> =0%	P=0.654 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	
General disorders and administrati on site conditions	Injection site haemorrhage	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
General disorders and administrati on site conditions	Injection site haemorrhage	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Nervous system disorders			15.7% (7.6, 29.7)	10.5% (3.4, 28.1)	P=0.075 , I <sup>2</sup> =68.5 %	P=0.550 , I <sup>2</sup> =0%							
Nervous system disorders		Mild	13.0% (5.9, 26.2)	6.7% (1.7, 23.1)	P=0.119 , I <sup>2</sup> =58.9 %	P=1.000 , I <sup>2</sup> =0%	1.615 (0.307 - 8.495)	1.552 (0.333 - 7.227)	0.037 (-0.082 - 0.156)	P=0.338, I <sup>2</sup> =0%	P=0.350, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =297 0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Nervous system disorders		Moderate	2.7% (0.5, 12.3)	5.2% (1.0, 22.0)	P=0.671, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	0.500 (0.029 - 8.602)	0.517 (0.035 - 7.703)	-0.016 (-0.088 - 0.056)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Nervous system disorders		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Headache		13.8% (6.0, 28.4)	6.7% (1.7, 23.1)	P=0.096, I <sup>2</sup> =63.8%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Headache	Mild	10.8% (4.3, 24.5)	5.2% (1.0, 22.0)	P=0.141, I <sup>2</sup> =53.9%	P=0.654, I <sup>2</sup> =0%	2.069 (0.237 - 18.080)	2.069 (0.231 - 18.511)	0.036 (-0.058 - 0.130)	P=0.099, I <sup>2</sup> =6335%	P=0.102, I <sup>2</sup> =6263%	P=0.070, I <sup>2</sup> =6964%	
Nervous system disorders	Headache	Moderate	2.7% (0.5, 12.3)	5.2% (1.0, 22.0)	P=0.671, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	0.500 (0.029 - 8.602)	0.517 (0.035 - 7.703)	-0.016 (-0.088 - 0.056)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Nervous system disorders	Headache	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Dizziness		3.4% (0.9, 12.8)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Dizziness	Mild	3.4% (0.9, 12.8)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.034 (-0.012 - 0.081)	P=NA, I <sup>2</sup> =NA %	P=NA, I <sup>2</sup> =NA %	P=0.706, I <sup>2</sup> =0%	
Nervous system disorders	Dizziness	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Nervous system disorders	Dizziness	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Post-traumatic headache		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Nervous system disorders	Post-traumatic headache	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Nervous system disorders	Post-traumatic headache	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Post-traumatic headache	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Nervous system disorders	Migraine		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Migraine	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Migraine	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Migraine	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Tremor		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Nervous system disorders	Tremor	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Tremor	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Nervous system disorders	Tremor	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications			15.7% (7.6, 29.7)	6.7% (1.7, 23.1)	P=0.075, I <sup>2</sup> =68.5%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Injury, poisoning and procedural complications		Mild	10.3% (4.3, 22.7)	6.7% (1.7, 23.1)	P=0.193, I <sup>2</sup> =41%	P=1.000, I <sup>2</sup> =0%	1.321 (0.241 - 7.233)	1.293 (0.266 - 6.275)	0.020 (-0.095 - 0.134)	P=0.419, I <sup>2</sup> =0%	P=0.426, I <sup>2</sup> =0%	P=0.362, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications		Moderate	5.2% (1.5, 16.3)	3.1% (0.4, 19.1)	P=0.358, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.034 (-0.012 - 0.081)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Injury, poisoning and procedural complications	Head injury		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Head injury	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Head injury	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Injury, poisoning and procedural complications	Head injury	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Post-traumatic pain		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Post-traumatic pain	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Injury, poisoning and procedural complications	Post-traumatic pain	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Post-traumatic pain	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal bite		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Injury, poisoning and procedural complications	Animal bite	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Animal bite	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal bite	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Injury, poisoning and procedural complications	Arthropod bite		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Arthropod bite	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Arthropod bite	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Injury, poisoning and procedural complications	Arthropod bite	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Contusion		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Contusion	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Injury, poisoning and procedural complications	Contusion	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Contusion	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ligament sprain		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Injury, poisoning and procedural complications	Ligament sprain	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ligament sprain	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ligament sprain	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Injury, poisoning and procedural complications	Skin laceration		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Skin laceration	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Skin laceration	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Injury, poisoning and procedural complications	Skin laceration	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ankle fracture		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ankle fracture	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Injury, poisoning and procedural complications	Ankle fracture	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Ankle fracture	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Concussion		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Injury, poisoning and procedural complications	Concussion	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Concussion	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Concussion	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Injury, poisoning and procedural complications	Face injury		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Face injury	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Face injury	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Injury, poisoning and procedural complications	Face injury	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Laceration		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Laceration	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Injury, poisoning and procedural complications	Laceration	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Laceration	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Meniscus injury		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatotropin Mean (95%CI)	Daily somatotropin Mean (95%CI)	Lonapeg somatotropin	Daily somatotropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Injury, poisoning and procedural complications	Meniscus injury	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Meniscus injury	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Meniscus injury	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Injury, poisoning and procedural complications	Radius fracture		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Radius fracture	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Radius fracture	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Injury, poisoning and procedural complications	Radius fracture	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Thermal burn		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Thermal burn	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Injury, poisoning and procedural complications	Thermal burn	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Thermal burn	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Upper limb fracture		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Injury, poisoning and procedural complications	Upper limb fracture	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Upper limb fracture	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Upper limb fracture	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Injury, poisoning and procedural complications	Burns first degree		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns first degree	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Burns first degree	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Injury, poisoning and procedural complications	Burns first degree	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns second degree		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Burns second degree	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Injury, poisoning and procedural complications	Burns second degree	Moderate	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Burns second degree	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Fall		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Injury, poisoning and procedural complications	Fall	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Injury, poisoning and procedural complications	Fall	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Fall	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Injury, poisoning and procedural complications	Muscle strain		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Muscle strain	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Muscle strain	Moderate	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Injury, poisoning and procedural complications	Muscle strain	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Wrist fracture		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Wrist fracture	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Injury, poisoning and procedural complications	Wrist fracture	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Wrist fracture	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Eye injury		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Injury, poisoning and procedural complications	Eye injury	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Eye injury	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Eye injury	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Injury, poisoning and procedural complications	Joint injury		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Joint injury	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Joint injury	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Injury, poisoning and procedural complications	Joint injury	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal scratch		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal scratch	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Injury, poisoning and procedural complications	Animal scratch	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Injury, poisoning and procedural complications	Animal scratch	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders			5.5% (1.8, 15.6)	3.1% (0.4, 19.1)	P=0.561, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Skin and subcutaneous tissue disorders		Mild	5.5% (1.8, 15.6)	3.1% (0.4, 19.1)	P=0.561, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.052 (-0.005 - 0.109)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.576, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders		Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash		5.2% (1.5, 16.3)	3.1% (0.4, 19.1)	P=0.358, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Skin and subcutaneous tissue disorders	Rash	Mild	5.2% (1.5, 16.3)	3.1% (0.4, 19.1)	P=0.358, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.034 (-0.012 - 0.081)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Rash	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Skin and subcutaneous tissue disorders	Urticaria	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis allergic		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Skin and subcutaneous tissue disorders	Dermatitis allergic	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis allergic	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis allergic	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Skin and subcutaneous tissue disorders	Eczema		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Eczema	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Eczema	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Eczema	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Skin and subcutaneous tissue disorders	Dermatitis contact		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis contact	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis contact	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis contact	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Skin and subcutaneous tissue disorders	Urticaria papular		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria papular	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Skin and subcutaneous tissue disorders	Urticaria papular	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria papular	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Skin and subcutaneous tissue disorders	Cafe au lait spots		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Cafe au lait spots	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Cafe au lait spots	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Skin and subcutaneous tissue disorders	Cafe au lait spots	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Keratosis pilaris		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Keratosis pilaris	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Keratosis pilaris	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Skin and subcutaneous tissue disorders	Keratosis pilaris	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Petechiae		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Petechiae	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Petechiae	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Skin and subcutaneous tissue disorders	Petechiae	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Pityriasis alba		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Pityriasis alba	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Pityriasis alba	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Skin and subcutaneous tissue disorders	Pityriasis alba	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash erythematous		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash erythematous	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Skin and subcutaneous tissue disorders	Rash erythematous	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash erythematous	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash pruritic		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash pruritic	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Skin and subcutaneous tissue disorders	Rash pruritic	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Rash pruritic	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Skin and subcutaneous tissue disorders	Dermatitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dermatitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dyshidrotic eczema		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria chronic		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Skin and subcutaneous tissue disorders	Urticaria chronic	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria chronic	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Skin and subcutaneous tissue disorders	Urticaria chronic	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders			5.5% (1.8, 15.6)	5.2% (1.0, 22.0)	P=0.561, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Eye disorders		Mild	5.5% (1.8, 15.6)	5.2% (1.0, 22.0)	P=0.561, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	1.571 (0.159 - 15.552)	1.552 (0.166 - 14.494)	0.018 (-0.068 - 0.105)	P=0.384, I <sup>2</sup> =0%	P=0.382, I <sup>2</sup> =0%	P=0.390, I <sup>2</sup> =0%	
Eye disorders		Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Refraction disorder		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Refraction disorder	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Eye disorders	Refraction disorder	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Refraction disorder	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Strabismus		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Strabismus	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Strabismus	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Eye disorders	Strabismus	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Conjunctivitis allergic		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Conjunctivitis allergic	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Conjunctivitis allergic	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Conjunctivitis allergic	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Eye disorders	Eye swelling		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Eye swelling	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Eye swelling	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Eye swelling	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Myopia		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Eye disorders	Myopia	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Myopia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Myopia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Papilloedema		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Papilloedema	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Eye disorders	Papilloedema	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Papilloedema	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Hypermetropia		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Hypermetropia	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Hypermetropia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Eye disorders	Hypermetropia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Astigmatism		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Astigmatism	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Astigmatism	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Astigmatism	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Eye disorders	Eye haemorrhage		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye haemorrhage	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Eye haemorrhage	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye haemorrhage	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Eye disorders	Corneal epithelium defect		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Corneal epithelium defect	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Corneal epithelium defect	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Corneal epithelium defect	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Eye pain		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Eye disorders	Eye pain	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Eye pain	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Eye pain	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Vitreous opacities		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Eye disorders	Vitreous opacities	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Eye disorders	Vitreous opacities	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Vitreous opacities	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Xerophthalmia		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Xerophthalmia	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Xerophthalmia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Eye disorders	Xerophthalmia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Vernal keratoconjunctivitis		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Eye disorders	Vernal keratoconjunctivitis	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Eye disorders	Vernal keratoconjunctivitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Eye disorders	Vernal keratoconjunctivitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Musculoskel etal and connective tissue disorders			6.9% (2.6, 17.0)	9.9% (2.8, 29.0)	P=1.000 , I <sup>2</sup> =0%	P=0.336 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders		Mild	6.9% (2.6, 17.0)	9.9% (2.8, 29.0)	P=1.000 , I <sup>2</sup> =0%	P=0.336 , I <sup>2</sup> =0%	1.037 (0.179 - 6.016)	1.034 (0.201 - 5.328)	0.002 (-0.108 - 0.113)	P=0.335, I <sup>2</sup> =0%	P=0.337, I <sup>2</sup> =0%	P=0.316, I <sup>2</sup> =65%	
Musculoskel etal and connective tissue disorders		Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Musculoskeletal and connective tissue disorders		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Pain in extremity		2.7% (0.5, 12.3)	9.9% (2.8, 29.0)	P=0.671, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Pain in extremity	Mild	2.7% (0.5, 12.3)	9.9% (2.8, 29.0)	P=0.671, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	0.259 (0.024 - 2.796)	0.259 (0.023 - 2.852)	-0.049 (-0.146 - 0.047)	P=0.198, I <sup>2</sup> =396 4%	P=0.201, I <sup>2</sup> =387 4%	P=0.133, I <sup>2</sup> =558 0%	



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Musculoskel etal and connective tissue disorders	Pain in extremity	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Pain in extremity	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Arthralgia		5.5% (1.8, 15.6)	3.1% (0.4, 19.1)	P=0.561 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Musculoskeletal and connective tissue disorders	Arthralgia	Mild	5.5% (1.8, 15.6)	3.1% (0.4, 19.1)	P=0.561, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.052 (-0.005 - 0.109)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.576, I <sup>2</sup> =0%	
Musculoskeletal and connective tissue disorders	Arthralgia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthralgia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Musculoskel etal and connective tissue disorders	Musculoskel etal pain		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Musculoskel etal pain	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Musculoskel etal pain	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Musculoskel etal and connective tissue disorders	Musculoskel etal pain	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Neck pain		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Neck pain	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Musculoskeletal and connective tissue disorders	Neck pain	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Neck pain	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthritis reactive		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Musculoskeletal and connective tissue disorders	Arthritis reactive	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthritis reactive	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Musculoskeletal and connective tissue disorders	Arthritis reactive	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Musculoskel etal and connective tissue disorders	Back pain		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Back pain	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Back pain	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Musculoskel etal and connective tissue disorders	Back pain	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Neck mass		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Neck mass	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Musculoskel etal and connective tissue disorders	Neck mass	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Neck mass	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Pain in jaw		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Musculoskel etal and connective tissue disorders	Pain in jaw	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Pain in jaw	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Pain in jaw	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Musculoskel etal and connective tissue disorders	Synovial cyst		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Synovial cyst	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Synovial cyst	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Musculoskel etal and connective tissue disorders	Synovial cyst	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Scoliosis		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Scoliosis	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Musculoskel etal and connective tissue disorders	Scoliosis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Musculoskel etal and connective tissue disorders	Scoliosis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Metabolism and nutrition disorders			16.8% (7.9, 32.2)	9.9% (2.8, 29.0)	P=0.068 , I <sup>2</sup> =70%	P=0.336 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Metabolism and nutrition disorders		Mild	16.8% (7.9, 32.2)	9.9% (2.8, 29.0)	P=0.068, I <sup>2</sup> =70%	P=0.336, I <sup>2</sup> =0%	1.696 (0.298 - 9.649)	1.552 (0.355 - 6.775)	0.037 (-0.076 - 0.150)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders		Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypertriglyceridaemia		7.9% (2.8, 20.5)	3.1% (0.4, 19.1)	P=0.216, I <sup>2</sup> =34.6%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

					Lonapegsomatropin vs. Daily somatropin								
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Metabolism and nutrition disorders	Hypertriglyceridaemia	Mild	7.9% (2.8, 20.5)	3.1% (0.4, 19.1)	P=0.216, I <sup>2</sup> =34.6%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.052 (-0.005 - 0.109)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Hypertriglyceridaemia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypertriglyceridaemia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypercholesterolaemia		5.2% (1.5, 16.3)	9.9% (2.8, 29.0)	P=0.358, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Metabolism and nutrition disorders	Hypercholesterolaemia	Mild	5.2% (1.5, 16.3)	9.9% (2.8, 29.0)	P=0.358, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	0.481 (0.061 - 3.810)	0.517 (0.081 - 3.317)	-0.032 (-0.131 - 0.066)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Hypercholesterolaemia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hypercholesterolaemia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Metabolism and nutrition disorders	Hyperuricaemia		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperuricaemia	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Hyperuricaemia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperuricaemia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Metabolism and nutrition disorders	Decreased appetite		2.7% (0.5, 12.3)	5.2% (1.0, 22.0)	P=0.671, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Decreased appetite	Mild	2.7% (0.5, 12.3)	5.2% (1.0, 22.0)	P=0.671, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	0.500 (0.029 - 8.602)	0.517 (0.035 - 7.703)	-0.016 (-0.088 - 0.056)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Metabolism and nutrition disorders	Decreased appetite	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Decreased appetite	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Metabolism and nutrition disorders	Polydipsia		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Polydipsia	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Polydipsia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Polydipsia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Metabolism and nutrition disorders	Calcium deficiency		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Calcium deficiency	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Calcium deficiency	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Metabolism and nutrition disorders	Calcium deficiency	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperglycaemia		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperglycaemia	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperglycaemia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Metabolism and nutrition disorders	Hyperglycaemia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperlipidaemia		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperlipidaemia	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Metabolism and nutrition disorders	Hyperlipidaemia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Metabolism and nutrition disorders	Hyperlipidaemia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders			7.9% (2.8, 20.5)	9.9% (2.8, 29.0)	P=0.216, I <sup>2</sup> =34.6%	P=0.336, I <sup>2</sup> =0%							
Endocrine disorders		Mild	2.7% (0.5, 12.3)	9.9% (2.8, 29.0)	P=0.671, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	0.232 (0.019 - 2.797)	0.259 (0.025 - 2.627)	-0.049 (-0.144 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders		Moderate	5.2% (1.5, 16.3)	3.1% (0.4, 19.1)	P=0.358, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.034 (-0.012 - 0.081)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Endocrine disorders		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Secondary hypothyroidism		5.2% (1.5, 16.3)	5.2% (1.0, 22.0)	P=0.358, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Endocrine disorders	Secondary hypothyroidism	Mild	2.7% (0.5, 12.3)	5.2% (1.0, 22.0)	P=0.671, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	0.500 (0.029 - 8.602)	0.517 (0.035 - 7.703)	-0.016 (-0.088 - 0.056)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Secondary hypothyroidism	Moderate	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Endocrine disorders	Secondary hypothyroidism	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Hypothyroidism		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Endocrine disorders	Hypothyroidism	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Hypothyroidism	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Hypothyroidism	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Endocrine disorders	Diabetes insipidus		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Diabetes insipidus	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Diabetes insipidus	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Diabetes insipidus	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Secondary adrenocortical insufficiency		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Endocrine disorders	Secondary adrenocortical insufficiency	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Secondary adrenocortical insufficiency	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Secondary adrenocortical insufficiency	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Adrenal insufficiency		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Adrenal insufficiency	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Endocrine disorders	Adrenal insufficiency	Moderate	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Endocrine disorders	Adrenal insufficiency	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Precocious puberty		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Precocious puberty	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Endocrine disorders	Precocious puberty	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Endocrine disorders	Precocious puberty	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders			5.5% (1.8, 15.6)	10.5% (3.4, 28.1)	P=0.561, I <sup>2</sup> =0%	P=0.550, I <sup>2</sup> =0%							
Blood and lymphatic system disorders		Mild	5.5% (1.8, 15.6)	10.5% (3.4, 28.1)	P=0.561, I <sup>2</sup> =0%	P=0.550, I <sup>2</sup> =0%	0.494 (0.094 - 2.592)	0.517 (0.110 - 2.426)	-0.048 (-0.170 - 0.074)	P=0.404, I <sup>2</sup> =0%	P=0.407, I <sup>2</sup> =0%	P=0.406, I <sup>2</sup> =0%	
Blood and lymphatic system disorders		Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Blood and lymphatic system disorders		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Anaemia		2.7% (0.5, 12.3)	6.7% (1.7, 23.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Anaemia	Mild	2.7% (0.5, 12.3)	6.7% (1.7, 23.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	0.246 (0.021 - 2.855)	0.259 (0.024 - 2.738)	-0.049 (-0.145 - 0.046)	P=0.585, I <sup>2</sup> =0%	P=0.579, I <sup>2</sup> =0%	P=0.666, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Blood and lymphatic system disorders	Anaemia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Anaemia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Iron deficiency anaemia		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Iron deficiency anaemia	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Blood and lymphatic system disorders	Iron deficiency anaemia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Iron deficiency anaemia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Neutropenia		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Neutropenia	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Blood and lymphatic system disorders	Neutropenia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Neutropenia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphaden opathy		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphaden opathy	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Blood and lymphatic system disorders	Lymphadenopathy	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenopathy	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Granulocytopenia		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Blood and lymphatic system disorders	Granulocytopenia	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Granulocytopenia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Granulocytopenia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenitis		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Blood and lymphatic system disorders	Lymphadenitis	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Blood and lymphatic system disorders	Lymphadenitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Lymphadenitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Hypochromic anaemia		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Blood and lymphatic system disorders	Hypochromic anaemia	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Hypochromic anaemia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Hypochromic anaemia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Thymus disorder		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatotropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatotropin Mean (95%CI)	Daily somatotropin Mean (95%CI)	Lonapeg somatotropin	Daily somatotropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Blood and lymphatic system disorders	Thymus disorder	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Thymus disorder	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Blood and lymphatic system disorders	Thymus disorder	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders			2.7% (0.5, 12.3)	6.7% (1.7, 23.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Immune system disorders		Mild	2.7% (0.5, 12.3)	6.7% (1.7, 23.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	0.246 (0.021 - 2.855)	0.259 (0.024 - 2.738)	-0.049 (-0.145 - 0.046)	P=0.585, I <sup>2</sup> =0%	P=0.579, I <sup>2</sup> =0%	P=0.666, I <sup>2</sup> =0%	
Immune system disorders		Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Seasonal allergy		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Immune system disorders	Seasonal allergy	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Immune system disorders	Seasonal allergy	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Seasonal allergy	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Hypersensitivity		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Immune system disorders	Hypersensitivity	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Immune system disorders	Hypersensitivity	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Hypersensitivity	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Allergy to animal		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Allergy to animal	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Immune system disorders	Allergy to animal	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Allergy to animal	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Food allergy		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Food allergy	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Immune system disorders	Food allergy	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Immune system disorders	Food allergy	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders			5.2% (1.5, 16.3)	3.1% (0.4, 19.1)	P=0.358, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders		Mild	5.2% (1.5, 16.3)	3.1% (0.4, 19.1)	P=0.358, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.034 (-0.012 - 0.081)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Reproductive system and breast disorders		Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Reproductive system and breast disorders		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Penile adhesion		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Penile adhesion	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Penile adhesion	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Reproductive system and breast disorders	Penile adhesion	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Gynaecomastia		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Gynaecomastia	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Gynaecomastia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Reproductive system and breast disorders	Gynaecomastia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Genital discomfort		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Genital discomfort	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Reproductive system and breast disorders	Genital discomfort	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Genital discomfort	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Balanoposthitis		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Balanoposthitis	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Reproductive system and breast disorders	Balanoposthitis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Balanoposthitis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Pelvic fluid collection		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Pelvic fluid collection	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Reproductive system and breast disorders	Pelvic fluid collection	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Pelvic fluid collection	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Testicular appendage torsion		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Testicular appendage torsion	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Reproductive system and breast disorders	Testicular appendage torsion	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Reproductive system and breast disorders	Testicular appendage torsion	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders			2.7% (0.5, 12.3)	5.2% (1.0, 22.0)	P=0.671, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Ear and labyrinth disorders		Mild	2.7% (0.5, 12.3)	5.2% (1.0, 22.0)	P=0.671, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	0.500 (0.029 - 8.602)	0.517 (0.035 - 7.703)	-0.016 (-0.088 - 0.056)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Ear and labyrinth disorders		Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Ear pain		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Ear pain	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Ear pain	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Ear and labyrinth disorders	Ear pain	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Cerumen impaction		1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Cerumen impaction	Mild	1.7% (0.2, 10.9)	5.2% (1.0, 22.0)	P=1.000, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.033 (-0.098 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Ear and labyrinth disorders	Cerumen impaction	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Ear and labyrinth disorders	Cerumen impaction	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Motion sickness		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Motion sickness	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Ear and labyrinth disorders	Motion sickness	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Ear and labyrinth disorders	Motion sickness	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Psychiatric disorders			5.2% (1.5, 16.3)	3.1% (0.4, 19.1)	P=0.358, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders		Mild	5.2% (1.5, 16.3)	3.1% (0.4, 19.1)	P=0.358, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.034 (-0.012 - 0.081)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Psychiatric disorders		Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Attention deficit/hyperactivity disorder		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Psychiatric disorders	Attention deficit/hyperactivity disorder	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Psychiatric disorders	Attention deficit/hyperactivity disorder	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Attention deficit/hyperactivity disorder	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Affect lability		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Psychiatric disorders	Affect lability	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Affect lability	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Affect lability	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Depressive symptom		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Depressive symptom	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Psychiatric disorders	Depressive symptom	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Depressive symptom	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Enuresis		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Psychiatric disorders	Enuresis	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Psychiatric disorders	Enuresis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Psychiatric disorders	Enuresis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders			2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders		Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Cardiac disorders		Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Cardiac disorders	Sinoatrial block		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinoatrial block	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinoatrial block	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinoatrial block	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinus tachycardia		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Cardiac disorders	Sinus tachycardia	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinus tachycardia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Sinus tachycardia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Tachycardia		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Tachycardia	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Cardiac disorders	Tachycardia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Tachycardia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Wandering pacemaker		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Wandering pacemaker	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Wandering pacemaker	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Cardiac disorders	Wandering pacemaker	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Myocarditis		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Cardiac disorders	Myocarditis	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Cardiac disorders	Myocarditis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Cardiac disorders	Myocarditis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			5.2% (1.5, 16.3)	3.1% (0.4, 19.1)	P=0.358, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Mild	5.2% (1.5, 16.3)	3.1% (0.4, 19.1)	P=0.358 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.034 (-0.012 - 0.081)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma		5.2% (1.5, 16.3)	3.1% (0.4, 19.1)	P=0.358, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Mild	5.2% (1.5, 16.3)	3.1% (0.4, 19.1)	P=0.358 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.034 (-0.012 - 0.081)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000 , I <sup>2</sup> =0%	P=1.000 , I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders			2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders		Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Renal and urinary disorders		Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Polyuria		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Polyuria	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Polyuria	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Renal and urinary disorders	Polyuria	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Pollakiuria		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Pollakiuria	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Renal and urinary disorders	Pollakiuria	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Pollakiuria	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Renal and urinary disorders	Nocturia		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Nocturia	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Nocturia	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Renal and urinary disorders	Nocturia	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders			2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Vascular disorders		Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Vascular disorders		Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Hypotension		2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Vascular disorders	Hypotension	Mild	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Vascular disorders	Hypotension	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Hypotension	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Cyanosis		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Cyanosis	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Vascular disorders	Cyanosis	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Vascular disorders	Cyanosis	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders			1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders		Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interactio n
Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL													
Congenital, familial and genetic disorders		Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Buried penis syndrome		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Buried penis syndrome	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatro pin Mean (95%CI)	Daily somatro pin Mean (95%CI)	Lonapeg somatro pin	Daily somatro pin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Congenital, familial and genetic disorders	Buried penis syndrome	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Buried penis syndrome	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Supernumerary teeth		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Supernumerary teeth	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Congenital, familial and genetic disorders	Supernumerary teeth	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Congenital, familial and genetic disorders	Supernumerary teeth	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders			1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders		Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL													
Hepatobiliary disorders		Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders		Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders	Hepatomegaly		1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders	Hepatomegaly	Mild	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Hepatobiliary disorders	Hepatomegaly	Moderate	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.22.m Treatment Emergent Adverse Events by Maximum Severity: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration

							Lonapegsomatropin vs. Daily somatropin						
			Meta Analysis		Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PM's Q, I <sup>2</sup> )			
System Organ Class	Preferred Term	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI]	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: $\geq$ 8 ng/mL													
Hepatobiliary disorders	Hepatomegaly	Severe	1.7% (0.2, 10.9)	3.1% (0.4, 19.1)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
<p>Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology.                      meta-analysis for interaction was performed based on RRs from different subgroups.                      Due to convergent issue, inverse variance method was used for pooling studies than generalized linear mixed model (GLMM). This may cause different estimate than using GLMM.</p>													



Table 1.30.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years												
Redness	ANY	6.0% (2.3, 14.9)	11.1% (4.2, 26.1)	P=0.594, I <sup>2</sup> =0%	P=0.039, I <sup>2</sup> =0%	0.512 (0.123 - 2.132)	0.535 (0.142 - 2.016) 0.356	-0.052 (-0.171 - 0.067)	P=0.147, I <sup>2</sup> =5235%	P=0.159, I <sup>2</sup> =4967%	P=0.071, I <sup>2</sup> =6937%	P=0.014
Redness	MILD	6.0% (2.3, 14.9)	11.1% (4.2, 26.1)	P=0.594, I <sup>2</sup> =0%	P=0.039, I <sup>2</sup> =0%	0.512 (0.123 - 2.132)	0.535 (0.142 - 2.016) 0.356	-0.052 (-0.171 - 0.067)	P=0.147, I <sup>2</sup> =5235%	P=0.159, I <sup>2</sup> =4967%	P=0.071, I <sup>2</sup> =6937%	P=0.018
Redness	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.556
Redness	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.30.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years												
Bruising	ANY	6.0% (2.3, 14.9)	2.8% (0.4, 17.3)	P=0.589, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	2.204 (0.235 - 20.662)	2.118 (0.250 - 17.969) 0.491	0.031 (-0.046 - 0.109)	P=0.770, I <sup>2</sup> =0%	P=0.769, I <sup>2</sup> =0%	P=0.888, I <sup>2</sup> =0%	P=0.260
Bruising	MILD	6.0% (2.3, 14.9)	0.0%	P=0.589, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA) NA	0.059 (0.003 - 0.116)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.591, I <sup>2</sup> =0%	P=0.175
Bruising	MODERATE	0.0%	2.8% (0.4, 17.3)	P=1.000, I <sup>2</sup> =0%	P=0.317, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA) NA	-0.028 (-0.082 - 0.026)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.737

Table 1.30.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years												
Bruising	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Swelling	ANY	6.0% (2.3, 14.9)	11.1% (4.2, 26.1)	P=0.049, I <sup>2</sup> =0%	P=0.039, I <sup>2</sup> =0%	0.474 (0.106 - 2.112)	0.524 (0.145 - 1.896) 0.324	-0.053 (-0.168 - 0.061)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.296
Swelling	MILD	6.0% (2.3, 14.9)	11.1% (4.2, 26.1)	P=0.049, I <sup>2</sup> =0%	P=0.039, I <sup>2</sup> =0%	0.474 (0.106 - 2.112)	0.524 (0.145 - 1.896) 0.324	-0.053 (-0.168 - 0.061)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.296
Swelling	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986
Swelling	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.986

Table 1.30.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years												
Other	ANY	3.0% (0.7, 11.2)	8.3% (2.7, 22.9)	P=0.711, I <sup>2</sup> =0%	P=0.077, I <sup>2</sup> =0%	0.341 (0.056 - 2.088)	0.357 (0.063 - 2.026) 0.245	-0.054 (-0.154 - 0.046)	P=0.233, I <sup>2</sup> =2983 %	P=0.241, I <sup>2</sup> =2741 %	P=0.154, I <sup>2</sup> =5074 %	P=0.309
Overall number of abnormal injection-site reactions		14.9% (8.2, 25.6)	19.4% (9.6, 35.5)	P=0.850, I <sup>2</sup> =0%	P=0.005, I <sup>2</sup> =0%	0.722 (0.251 - 2.072)	0.762 (0.318 - 1.825) 0.541	-0.047 (-0.203 - 0.109)	P=0.075, I <sup>2</sup> =6841 %	P=0.088, I <sup>2</sup> =6555 %	P=0.016, I <sup>2</sup> =8288 %	P=0.196

Table 1.30.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years												
Redness	ANY	19.6% (13.8, 27.0)	4.1% (1.3, 12.0)	P=0.004, I <sup>2</sup> =85.5%	P=0.741, I <sup>2</sup> =0%	5.755 (1.685 - 19.656)	4.745 (1.493 - 15.078) 0.008	0.154 (0.074 - 0.234)	P=0.466, I <sup>2</sup> =0%	P=0.547, I <sup>2</sup> =0%	P=0.017, I <sup>2</sup> =8258%	
Redness	MILD	18.1% (12.5, 25.4)	4.1% (1.3, 12.0)	P=0.002, I <sup>2</sup> =86.5%	P=0.741, I <sup>2</sup> =0%	5.231 (1.526 - 17.931)	4.392 (1.376 - 14.023) 0.012	0.139 (0.061 - 0.218)	P=0.395, I <sup>2</sup> =0%	P=0.465, I <sup>2</sup> =0%	P=0.010, I <sup>2</sup> =8490%	

Table 1.30.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years												
Redness	MODERATE	1.4% (0.4, 5.6)	0.0%	P=0.819, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.015 (-0.005 - 0.034)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.706, I <sup>2</sup> =0%	
Redness	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Bruising	ANY	0.7% (0.1, 5.0)	2.7% (0.7, 10.3)	P=0.187, I <sup>2</sup> =0%	P=0.828, I <sup>2</sup> =0%	0.260 (0.023 - 2.936)	0.266 (0.025 - 2.863) 0.275	-0.020 (-0.060 - 0.020)	P=0.580, I <sup>2</sup> =0%	P=0.576, I <sup>2</sup> =0%	P=0.744, I <sup>2</sup> =0%	
Bruising	MILD	0.7% (0.1, 5.0)	2.7% (0.7, 10.3)	P=0.187, I <sup>2</sup> =0%	P=0.828, I <sup>2</sup> =0%	0.260 (0.023 - 2.936)	0.266 (0.025 - 2.863) 0.275	-0.020 (-0.060 - 0.020)	P=0.580, I <sup>2</sup> =0%	P=0.576, I <sup>2</sup> =0%	P=0.744, I <sup>2</sup> =0%	
Bruising	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.30.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years												
Bruising	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Swelling	ANY	5.1% (2.4, 10.3)	1.4% (0.2, 9.1)	P=0.103, I <sup>2</sup> =48.9%	P=0.188, I <sup>2</sup> =0%	3.752 (0.463 - 30.420)	3.704 (0.456 - 30.095) 0.221	0.037 (-0.009 - 0.083)	P=0.148, I <sup>2</sup> =5222%	P=0.147, I <sup>2</sup> =5248%	P=0.087, I <sup>2</sup> =6585%	
Swelling	MILD	5.1% (2.4, 10.3)	1.4% (0.2, 9.1)	P=0.103, I <sup>2</sup> =48.9%	P=0.188, I <sup>2</sup> =0%	3.752 (0.463 - 30.420)	3.704 (0.456 - 30.095) 0.221	0.037 (-0.009 - 0.083)	P=0.148, I <sup>2</sup> =5222%	P=0.147, I <sup>2</sup> =5248%	P=0.087, I <sup>2</sup> =6585%	
Swelling	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Swelling	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.30.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years												
Other	ANY	3.6% (1.5, 8.4)	1.4% (0.2, 9.1)	P=0.288, I <sup>2</sup> =0%	P=0.188, I <sup>2</sup> =0%	2.676 (0.310 - 23.103)	2.648 (0.310 - 22.598) 0.373	0.022 (-0.019 - 0.064)	P=0.227, I <sup>2</sup> =3163%	P=0.225, I <sup>2</sup> =3207%	P=0.208, I <sup>2</sup> =3691%	
Overall number of abnormal injection-site reactions		23.2% (16.9, 31.0)	9.6% (4.6, 18.8)	P=0.002, I <sup>2</sup> =88.1%	P=0.412, I <sup>2</sup> =0%	2.764 (1.172 - 6.519)	2.414 (1.111 - 5.242) 0.026	0.135 (0.037 - 0.234)	P=0.025, I <sup>2</sup> =8000%	P=0.034, I <sup>2</sup> =7781%	P=0.004, I <sup>2</sup> =8779%	
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.												



Table 1.31.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Redness	ANY	21.9% (10.8, 39.3)	5.6% (0.8, 30.7)	P=0.090, I <sup>2</sup> =54.7%	P=0.193, I <sup>2</sup> =0%	4.204 (0.517 - 34.200)	3.958 (0.474 - 33.073) 0.204	0.159 (-0.024 - 0.342)	P=0.149, I <sup>2</sup> =5201 %	P=0.147, I <sup>2</sup> =5239 %	P=0.073, I <sup>2</sup> =6891 %	
Redness	MILD	21.9% (10.8, 39.3)	5.6% (0.8, 30.7)	P=0.090, I <sup>2</sup> =54.7%	P=0.193, I <sup>2</sup> =0%	4.204 (0.517 - 34.200)	3.958 (0.474 - 33.073) 0.204	0.159 (-0.024 - 0.342)	P=0.149, I <sup>2</sup> =5201 %	P=0.147, I <sup>2</sup> =5239 %	P=0.073, I <sup>2</sup> =6891 %	
Redness	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Redness	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.31.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Bruising	ANY	3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	0.500 (0.028 - 8.952)	0.526 (0.037 - 7.554) 0.637	-0.027 (-0.148 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Bruising	MILD	3.1% (0.4, 19.1)	5.6% (0.8, 30.7)	P=0.302, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	0.500 (0.028 - 8.952)	0.526 (0.037 - 7.554) 0.637	-0.027 (-0.148 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Bruising	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Bruising	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.31.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Swelling	ANY	6.3% (1.6, 21.8)	5.6% (0.8, 30.7)	P=0.140, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	1.114 (0.097 - 12.820)	1.114 (0.093 - 13.403) 0.932	0.006 (-0.131 - 0.143)	P=0.220, I <sup>2</sup> =3355%	P=0.228, I <sup>2</sup> =3129%	P=0.203, I <sup>2</sup> =3838%	
Swelling	MILD	6.3% (1.6, 21.8)	5.6% (0.8, 30.7)	P=0.140, I <sup>2</sup> =0%	P=0.193, I <sup>2</sup> =0%	1.114 (0.097 - 12.820)	1.114 (0.093 - 13.403) 0.932	0.006 (-0.131 - 0.143)	P=0.220, I <sup>2</sup> =3355%	P=0.228, I <sup>2</sup> =3129%	P=0.203, I <sup>2</sup> =3838%	
Swelling	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Swelling	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.31.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Other	ANY	9.4% (3.1, 25.4)	0.0%	P=0.068, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.090 (-0.010 - 0.189)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Overall number of abnormal injection-site reactions		34.4% (20.2, 52.1)	16.7% (5.5, 40.9)	P=0.005, I <sup>2</sup> =80.7%	P=0.396, I <sup>2</sup> =0%	2.332 (0.595 - 9.141)	2.023 (0.605 - 6.767) 0.253	0.168 (-0.080 - 0.417)	P=0.035, I <sup>2</sup> =7754 %	P=0.055, I <sup>2</sup> =7295 %	P=0.008, I <sup>2</sup> =8580 %	

Table 1.31.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Redness	ANY	13.9% (9.5, 19.9)	6.6% (3.0, 13.9)	P=0.006, I <sup>2</sup> =84.6%	P=0.379, I <sup>2</sup> =0%	2.257 (0.899 - 5.664)	2.112 (0.892 - 4.998) 0.089	0.073 (0.000 - 0.147)	P=0.042, I <sup>2</sup> =7580%	P=0.048, I <sup>2</sup> =7448%	P=0.011, I <sup>2</sup> =8450%	P=0.929
Redness	MILD	12.7% (8.5, 18.6)	6.6% (3.0, 13.9)	P=0.005, I <sup>2</sup> =85.4%	P=0.379, I <sup>2</sup> =0%	2.045 (0.809 - 5.170)	1.937 (0.811 - 4.624) 0.137	0.062 (-0.010 - 0.134)	P=0.034, I <sup>2</sup> =7769%	P=0.039, I <sup>2</sup> =7662%	P=0.010, I <sup>2</sup> =8506%	P=0.868

Table 1.31.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Redness	MODERATE	1.2% (0.3, 4.5)	0.0%	P=0.993, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA) NA	0.012 (-0.004 - 0.027)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.721, I <sup>2</sup> =0%	P=0.584
Redness	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Bruising	ANY	2.3% (0.9, 6.0)	2.2% (0.6, 8.4)	P=0.018, I <sup>2</sup> =0%	P=0.091, I <sup>2</sup> =0%	1.036 (0.182 - 5.885)	1.034 (0.197 - 5.434) 0.968	0.001 (-0.036 - 0.038)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.707
Bruising	MILD	2.3% (0.9, 6.0)	1.1% (0.2, 7.4)	P=0.018, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	2.120 (0.230 - 19.555)	2.069 (0.238 - 17.968) 0.51	0.012 (-0.019 - 0.042)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.503

Table 1.31.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Bruising	MODERATE	0.0%	1.1% (0.2, 7.4)	P=1.000, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.011 (-0.033 - 0.010)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.678
Bruising	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954
Swelling	ANY	5.2% (2.7, 9.7)	4.4% (1.7, 11.1)	P=0.745, I <sup>2</sup> =0%	P=0.016, I <sup>2</sup> =0%	1.186 (0.354 - 3.970)	1.175 (0.375 - 3.686) 0.782	0.008 (-0.046 - 0.061)	P=0.182, I <sup>2</sup> =4381%	P=0.182, I <sup>2</sup> =4378%	P=0.153, I <sup>2</sup> =5108%	P=0.942
Swelling	MILD	5.2% (2.7, 9.7)	4.4% (1.7, 11.1)	P=0.745, I <sup>2</sup> =0%	P=0.016, I <sup>2</sup> =0%	1.186 (0.354 - 3.970)	1.175 (0.375 - 3.686) 0.782	0.008 (-0.046 - 0.061)	P=0.182, I <sup>2</sup> =4381%	P=0.182, I <sup>2</sup> =4378%	P=0.153, I <sup>2</sup> =5108%	P=0.942
Swelling	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.954

Table 1.31.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I²)		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I²)			
Symptom	Severity	Lonapeg somatropi n Mean (95%CI)	Daily somatropi n Mean (95%CI)	Lonapeg somatropi n	Daily somatropi n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Swelling	SEVERE	0.0%	0.0%	P=1.000, I²=0%	P=1.000, I²=0%							P=0.954
Other	ANY	2.3% (0.9, 6.0)	4.4% (1.7, 11.1)	P=0.991, I²=0%	P=0.016, I²=0%	0.512 (0.126 - 2.082)	0.523 (0.135 - 2.031) 0.349	-0.021 (-0.069 - 0.027)	P=0.170, I²=4688%	P=0.176, I²=4539%	P=0.051, I²=7365%	P=0.276
Overall number of abnormal injection-site reactions		17.9% (12.9, 24.4)	12.1% (6.8, 20.5)	P=0.067, I²=69%	P=0.018, I²=77%	1.564 (0.755 - 3.237)	1.482 (0.776 - 2.828) 0.233	0.058 (-0.031 - 0.148)	P=0.006, I²=8691%	P=0.006, I²=8667%	P=0.002, I²=8929%	P=0.951
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.												



Table 1.32.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by baseline GH-stimulation strata

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL												
Redness	ANY	19.4% (11.3, 31.1)	14.7% (6.3, 30.8)	P=0.006, I <sup>2</sup> =78.2%	P=0.285, I <sup>2</sup> =10%	1.385 (0.461 - 4.163)	1.331 (0.504 - 3.512) 0.564	0.049 (-0.111 - 0.209)	P=0.022, I <sup>2</sup> =8095%	P=0.028, I <sup>2</sup> =7927%	P=0.013, I <sup>2</sup> =8384%	P=0.364
Redness	MILD	17.7% (10.1, 29.3)	14.7% (6.3, 30.8)	P=0.011, I <sup>2</sup> =75.3%	P=0.285, I <sup>2</sup> =10%	1.252 (0.411 - 3.821)	1.219 (0.456 - 3.264) 0.693	0.032 (-0.125 - 0.190)	P=0.028, I <sup>2</sup> =7928%	P=0.034, I <sup>2</sup> =7771%	P=0.020, I <sup>2</sup> =8160%	P=0.388

Table 1.32.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by baseline GH-stimulation strata

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL												
Redness	MODERATE	1.6% (0.2, 10.6)	0.0%	P=0.307, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.016 (-0.015 - 0.048)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.976
Redness	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Bruising	ANY	1.6% (0.2, 10.6)	5.9% (1.5, 20.7)	P=0.307, I <sup>2</sup> =0%	P=0.728, I <sup>2</sup> =0%	0.270 (0.024 - 3.031)	0.279 (0.027 - 2.906) 0.286	-0.043 (-0.128 - 0.043)	P=0.559, I <sup>2</sup> =0%	P=0.561, I <sup>2</sup> =0%	P=0.507, I <sup>2</sup> =0%	P=0.296
Bruising	MILD	1.6% (0.2, 10.6)	5.9% (1.5, 20.7)	P=0.307, I <sup>2</sup> =0%	P=0.728, I <sup>2</sup> =0%	0.270 (0.024 - 3.031)	0.279 (0.027 - 2.906) 0.286	-0.043 (-0.128 - 0.043)	P=0.559, I <sup>2</sup> =0%	P=0.561, I <sup>2</sup> =0%	P=0.507, I <sup>2</sup> =0%	P=0.243
Bruising	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.707

Table 1.32.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by baseline GH-stimulation strata

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL												
Bruising	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Swelling	ANY	6.5% (2.4, 16.0)	8.8% (2.9, 24.0)	P=0.038, I <sup>2</sup> =0%	P=0.012, I <sup>2</sup> =0%	0.734 (0.167 - 3.225)	0.734 (0.169 - 3.179) 0.679	-0.024 (-0.143 - 0.095)	P=0.034, I <sup>2</sup> =7770%	P=0.042, I <sup>2</sup> =7576%	P=0.009, I <sup>2</sup> =8538%	P=0.487
Swelling	MILD	6.5% (2.4, 16.0)	8.8% (2.9, 24.0)	P=0.038, I <sup>2</sup> =0%	P=0.012, I <sup>2</sup> =0%	0.734 (0.167 - 3.225)	0.734 (0.169 - 3.179) 0.679	-0.024 (-0.143 - 0.095)	P=0.034, I <sup>2</sup> =7770%	P=0.042, I <sup>2</sup> =7576%	P=0.009, I <sup>2</sup> =8538%	P=0.487
Swelling	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980
Swelling	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.980

Table 1.32.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by baseline GH-stimulation strata

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL												
Other	ANY	1.6% (0.2, 10.6)	2.9% (0.4, 18.1)	P=0.307, I <sup>2</sup> =0%	P=0.160, I <sup>2</sup> =0%	0.550 (0.036 - 8.507)	0.550 (0.037 - 8.287) 0.666	-0.013 (-0.080 - 0.053)	P=0.311, I <sup>2</sup> =252%	P=0.317, I <sup>2</sup> =0%	P=0.276, I <sup>2</sup> =1583%	P=0.857
Overall number of abnormal injection-site reactions		22.6% (13.9, 34.6)	26.5% (14.4, 43.5)	P=0.002, I <sup>2</sup> =82.4%	P=0.042, I <sup>2</sup> =74%	0.839 (0.338 - 2.078)	0.861 (0.403 - 1.841) 0.7	-0.037 (-0.230 - 0.156)	P=0.002, I <sup>2</sup> =8960%	P=0.004, I <sup>2</sup> =8796%	P=0.000, I <sup>2</sup> =9179%	P=0.290

Table 1.32.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by baseline GH-stimulation strata

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL												
Redness	ANY	13.3% (8.6, 19.9)	2.7% (0.7, 10.0)			5.333 (1.239 - 22.962)	4.987 (1.173 - 21.204) 0.03	0.106 (0.039 - 0.173)	P=0.107, I <sup>2</sup> =6142%	P=0.108, I <sup>2</sup> =6135%	P=0.028, I <sup>2</sup> =7924%	
Redness	MILD	12.6% (8.1, 19.1)	2.7% (0.7, 10.0)			4.986 (1.159 - 21.440)	4.720 (1.103 - 20.196) 0.036	0.099 (0.032 - 0.165)	P=0.083, I <sup>2</sup> =6682%	P=0.083, I <sup>2</sup> =6671%	P=0.015, I <sup>2</sup> =8313%	

Table 1.32.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by baseline GH-stimulation strata

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL												
Redness	MODERATE	0.7% (0.1, 4.8)	0.0%	P=0.255, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.007 (-0.007 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Redness	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Bruising	ANY	2.8% (1.1, 7.2)	1.3% (0.2, 8.9)	P=0.022, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	2.197 (0.237 - 20.349)	2.133 (0.247 - 18.451) 0.491	0.015 (-0.022 - 0.052)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Bruising	MILD	2.8% (1.1, 7.2)	0.0%	P=0.022, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.028 (0.001 - 0.055)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.32.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by baseline GH-stimulation strata

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL												
Bruising	MODERATE	0.0%	1.3% (0.2, 8.9)	P=1.000, I <sup>2</sup> =0%	P=0.260, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.039 - 0.013)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Bruising	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Swelling	ANY	4.9% (2.4, 9.9)	2.7% (0.7, 10.0)	P=0.294, I <sup>2</sup> =0.8%	P=0.109, I <sup>2</sup> =0%	1.915 (0.383 - 9.590)	1.854 (0.397 - 8.656) 0.432	0.023 (-0.028 - 0.073)	P=0.650, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	P=0.894, I <sup>2</sup> =0%	
Swelling	MILD	4.9% (2.4, 9.9)	2.7% (0.7, 10.0)	P=0.294, I <sup>2</sup> =0.8%	P=0.109, I <sup>2</sup> =0%	1.915 (0.383 - 9.590)	1.854 (0.397 - 8.656) 0.432	0.023 (-0.028 - 0.073)	P=0.650, I <sup>2</sup> =0%	P=0.644, I <sup>2</sup> =0%	P=0.894, I <sup>2</sup> =0%	
Swelling	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.32.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by baseline GH-stimulation strata

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL												
Swelling	SEVERE	0.0%	0.0%									
				P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Other	ANY	4.2% (1.9, 9.0)	4.0% (1.3, 11.7)	P=0.335, I <sup>2</sup> =0%	P=0.049, I <sup>2</sup> =0%	1.052 (0.257 - 4.299)	1.050 (0.265 - 4.155) 0.944	0.002 (-0.053 - 0.057)	P=0.111, I <sup>2</sup> =6055%	P=0.114, I <sup>2</sup> =6007%	P=0.076, I <sup>2</sup> =6818%	
Overall number of abnormal injection-site reactions		19.6% (13.9, 26.9)	6.7% (2.8, 15.0)	P=0.119, I <sup>2</sup> =57.8%	P=0.010, I <sup>2</sup> =0%	3.279 (1.228 - 8.757)	2.945 (1.168 - 7.422) 0.022	0.129 (0.041 - 0.216)	P=0.027, I <sup>2</sup> =7956%	P=0.025, I <sup>2</sup> =8002%	P=0.011, I <sup>2</sup> =8472%	
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.												



Table 1.33.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I²)		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I²)			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Redness	ANY	11.9% (7.6, 18.1)	8.3% (4.0, 16.5)	P=0.145, I²=51.7%	P=0.380, I²=0%	1.479 (0.594 - 3.683)	1.428 (0.618 - 3.301) 0.405	0.036 (-0.043 - 0.114)	P=0.140, I²=5403%	P=0.146, I²=5273%	P=0.103, I²=6249%	P=0.489
Redness	MILD	10.6% (6.6, 16.6)	8.3% (4.0, 16.5)	P=0.138, I²=52.9%	P=0.380, I²=0%	1.296 (0.513 - 3.276)	1.269 (0.540 - 2.982) 0.585	0.022 (-0.055 - 0.100)	P=0.133, I²=5580%	P=0.137, I²=5479%	P=0.102, I²=6259%	P=0.434

Table 1.33.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Redness	MODERATE	1.3% (0.3, 5.1)	0.0%	P=0.887, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.013 (-0.005 - 0.031)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.738, I <sup>2</sup> =0%	P=0.460
Redness	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Bruising	ANY	3.3% (1.4, 7.7)	2.4% (0.6, 9.0)	P=0.233, I <sup>2</sup> =14.4%	P=0.864, I <sup>2</sup> =0%	1.411 (0.269 - 7.406)	1.398 (0.278 - 7.030) 0.684	0.009 (-0.034 - 0.053)	P=0.419, I <sup>2</sup> =0%	P=0.421, I <sup>2</sup> =0%	P=0.365, I <sup>2</sup> =0%	P=0.509
Bruising	MILD	3.3% (1.4, 7.7)	1.2% (0.2, 8.0)	P=0.233, I <sup>2</sup> =14.4%	P=0.198, I <sup>2</sup> =0%	2.804 (0.329 - 23.904)	2.777 (0.331 - 23.271) 0.346	0.021 (-0.016 - 0.058)	P=0.217, I <sup>2</sup> =3439%	P=0.216, I <sup>2</sup> =3465%	P=0.179, I <sup>2</sup> =4468%	P=0.463

Table 1.33.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Bruising	MODERATE	0.0%	1.2% (0.2, 8.0)	P=1.000, I <sup>2</sup> =0%	P=0.279, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.012 (-0.035 - 0.011)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.819
Bruising	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Swelling	ANY	4.0% (1.8, 8.6)	6.0% (2.5, 13.5)	P=0.552, I <sup>2</sup> =0%	P=0.014, I <sup>2</sup> =0%	0.657 (0.193 - 2.237)	0.674 (0.213 - 2.136) 0.502	-0.019 (-0.078 - 0.040)	P=0.262, I <sup>2</sup> =2051%	P=0.270, I <sup>2</sup> =1792%	P=0.100, I <sup>2</sup> =6303%	P=0.519
Swelling	MILD	4.0% (1.8, 8.6)	6.0% (2.5, 13.5)	P=0.552, I <sup>2</sup> =0%	P=0.014, I <sup>2</sup> =0%	0.657 (0.193 - 2.237)	0.674 (0.213 - 2.136) 0.502	-0.019 (-0.078 - 0.040)	P=0.262, I <sup>2</sup> =2051%	P=0.270, I <sup>2</sup> =1792%	P=0.100, I <sup>2</sup> =6303%	P=0.519
Swelling	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908

Table 1.33.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Swelling	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.908
Other	ANY	3.3% (1.4, 7.7)	4.8% (1.8, 12.0)	P=0.103, I <sup>2</sup> =52.1%	P=0.028, I <sup>2</sup> =0%	0.690 (0.182 - 2.608)	0.693 (0.186 - 2.583) 0.585	-0.015 (-0.069 - 0.040)	P=0.047, I <sup>2</sup> =7473 %	P=0.050, I <sup>2</sup> =7401 %	P=0.019, I <sup>2</sup> =8189 %	P=0.728
Overall number of abnormal injection-site reactions		17.9% (12.6, 24.8)	15.5% (9.2, 24.9)	P=0.102, I <sup>2</sup> =61.9%	P=0.088, I <sup>2</sup> =61%	1.183 (0.579 - 2.420)	1.155 (0.624 - 2.135) 0.647	0.024 (-0.076 - 0.124)	P=0.026, I <sup>2</sup> =7993 %	P=0.028, I <sup>2</sup> =7923 %	P=0.016, I <sup>2</sup> =8287 %	P=0.380

Table 1.33.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Redness	ANY	24.2% (12.6, 41.5)	0.0%	P=0.001, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.263 (0.114 - 0.411)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Redness	MILD	24.2% (12.6, 41.5)	0.0%	P=0.001, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.263 (0.114 - 0.411)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Redness	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Redness	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.33.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Bruising	ANY	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Bruising	MILD	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Bruising	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Bruising	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Swelling	ANY	6.1% (1.5, 21.2)	0.0%	P=0.824, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA) NA	0.060 (-0.022 - 0.141)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.620, I <sup>2</sup> =0%	

Table 1.33.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Swelling	MILD	6.1% (1.5, 21.2)	0.0%	P=0.824, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA) NA	0.060 (-0.022 - 0.141)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.620, I <sup>2</sup> =0%	
Swelling	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Swelling	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Other	ANY	3.0% (0.4, 18.6)	0.0%	P=0.185, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Overall number of abnormal injection-site reactions		27.3% (14.8, 44.7)	0.0%	P=0.018, I <sup>2</sup> =74.4%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA) NA	0.289 (0.136 - 0.443)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.036, I <sup>2</sup> =7730%	

Table 1.33.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Redness	ANY	23.8% (10.3, 46.0)	0.0%	P=0.182, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA) NA	0.249 (0.064 - 0.434)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Redness	MILD	23.8% (10.3, 46.0)	0.0%	P=0.182, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA) NA	0.249 (0.064 - 0.434)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Redness	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Redness	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.33.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Bruising	ANY	0.0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.010, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA) NA	-0.104 (-0.284 - 0.075)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Bruising	MILD	0.0%	9.1% (1.3, 43.9)	P=1.000, I <sup>2</sup> =0%	P=0.010, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA) NA	-0.104 (-0.284 - 0.075)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Bruising	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Bruising	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.33.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Swelling	ANY	14.3% (4.7, 36.1)	0.0%	P=0.316, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.149 (-0.004 - 0.302)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Swelling	MILD	14.3% (4.7, 36.1)	0.0%	P=0.316, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.149 (-0.004 - 0.302)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Swelling	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Swelling	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.33.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Other	ANY	4.8% (0.7, 27.1)	0.0%	P=0.574, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA) NA	0.050 (-0.044 - 0.143)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Overall number of abnormal injection-site reactions		28.6% (13.4, 50.8)	9.1% (1.3, 43.9)	P=0.137, I <sup>2</sup> =0%	P=0.010, I <sup>2</sup> =0%	2.857 (0.371 - 22.022)	2.857 (0.413 - 19.766) 0.287	0.194 (-0.104 - 0.492)	P=0.041, I <sup>2</sup> =7594 %	P=0.031, I <sup>2</sup> =7863 %	P=0.013, I <sup>2</sup> =8389 %	
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.												

Table 1.34.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by peak stimulated GH concentration

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL												
Redness	ANY	16.3% (11.2, 23.2)	6.3% (2.7, 14.3)	P=0.002, I <sup>2</sup> =87%	P=0.582, I <sup>2</sup> =0%	2.845 (1.055 - 7.667)	2.582 (1.020 - 6.536) 0.045	0.100 (0.019 - 0.181)	P=0.061, I <sup>2</sup> =71.54%	P=0.073, I <sup>2</sup> =68.79%	P=0.008, I <sup>2</sup> =85.72%	P=0.550
Redness	MILD	15.0% (10.1, 21.7)	6.3% (2.7, 14.3)	P=0.001, I <sup>2</sup> =87.6%	P=0.582, I <sup>2</sup> =0%	2.569 (0.947 - 6.969)	2.368 (0.928 - 6.041) 0.071	0.087 (0.007 - 0.166)	P=0.047, I <sup>2</sup> =74.65%	P=0.056, I <sup>2</sup> =72.56%	P=0.006, I <sup>2</sup> =86.51%	P=0.655

Table 1.34.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by peak stimulated GH concentration

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL												
Redness	MODERATE	1.4% (0.3, 5.3)	0.0%	P=0.961, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	0.014 (-0.005 - 0.032)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.729, I <sup>2</sup> =0%	P=0.536
Redness	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.992
Bruising	ANY	2.0% (0.7, 6.1)	3.8% (1.2, 11.1)	P=0.517, I <sup>2</sup> =0%	P=0.509, I <sup>2</sup> =0%	0.526 (0.103 - 2.676)	0.537 (0.111 - 2.589) 0.438	-0.018 (-0.065 - 0.030)	P=0.990, I <sup>2</sup> =0%	P=0.996, I <sup>2</sup> =0%	P=0.775, I <sup>2</sup> =0%	P=0.487
Bruising	MILD	2.0% (0.7, 6.1)	2.5% (0.6, 9.6)	P=0.517, I <sup>2</sup> =0%	P=0.957, I <sup>2</sup> =0%	0.801 (0.131 - 4.902)	0.805 (0.137 - 4.721) 0.81	-0.005 (-0.046 - 0.037)	P=0.712, I <sup>2</sup> =0%	P=0.711, I <sup>2</sup> =0%	P=0.756, I <sup>2</sup> =0%	P=0.688

Table 1.34.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by peak stimulated GH concentration

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL												
Bruising	MODERATE	0.0%	1.3% (0.2, 8.4)	P=1.000, I <sup>2</sup> =0%	P=0.224, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.013 (-0.037 - 0.012)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.732
Bruising	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.992
Swelling	ANY	4.8% (2.3, 9.7)	5.1% (1.9, 12.7)	P=0.276, I <sup>2</sup> =7.5%	P=0.014, I <sup>2</sup> =0%	0.938 (0.270 - 3.262)	0.940 (0.281 - 3.149) 0.92	-0.003 (-0.063 - 0.057)	P=0.048, I <sup>2</sup> =7442%	P=0.050, I <sup>2</sup> =7387%	P=0.021, I <sup>2</sup> =8129%	P=0.395
Swelling	MILD	4.8% (2.3, 9.7)	5.1% (1.9, 12.7)	P=0.276, I <sup>2</sup> =7.5%	P=0.014, I <sup>2</sup> =0%	0.938 (0.270 - 3.262)	0.940 (0.281 - 3.149) 0.92	-0.003 (-0.063 - 0.057)	P=0.048, I <sup>2</sup> =7442%	P=0.050, I <sup>2</sup> =7387%	P=0.021, I <sup>2</sup> =8129%	P=0.395
Swelling	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.992

Table 1.34.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by peak stimulated GH concentration

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL												
Swelling	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.992
Other	ANY	2.7% (1.0, 7.0)	3.8% (1.2, 11.1)	P=0.332, I <sup>2</sup> =0%	P=0.034, I <sup>2</sup> =0%	0.712 (0.158 - 3.218)	0.716 (0.163 - 3.153) 0.659	-0.011 (-0.061 - 0.039)	P=0.094, I <sup>2</sup> =6425%	P=0.098, I <sup>2</sup> =6350%	P=0.054, I <sup>2</sup> =7309%	P=0.615
Overall number of abnormal injection-site reactions		19.7% (14.1, 26.9)	15.2% (8.8, 24.9)	P=0.001, I <sup>2</sup> =89.8%	P=0.040, I <sup>2</sup> =73%	1.348 (0.661 - 2.751)	1.300 (0.691 - 2.445) 0.416	0.046 (-0.060 - 0.151)	P=0.001, I <sup>2</sup> =9142%	P=0.001, I <sup>2</sup> =9090%	P=0.000, I <sup>2</sup> =9302%	P=0.487

Table 1.34.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by peak stimulated GH concentration

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL												
Redness	ANY	12.1% (5.9, 23.2)	6.7% (1.7, 23.1)	P=0.220, I <sup>2</sup> =27.2%	P=0.088, I <sup>2</sup> =0%	1.870 (0.376 - 9.299)	1.810 (0.390 - 8.409) 0.449	0.054 (-0.071 - 0.179)	P=0.121, I <sup>2</sup> =5847%	P=0.121, I <sup>2</sup> =5848%	P=0.094, I <sup>2</sup> =6442%	
Redness	MILD	12.1% (5.9, 23.2)	6.7% (1.7, 23.1)	P=0.220, I <sup>2</sup> =27.2%	P=0.088, I <sup>2</sup> =0%	1.870 (0.376 - 9.299)	1.810 (0.390 - 8.409) 0.449	0.054 (-0.071 - 0.179)	P=0.121, I <sup>2</sup> =5847%	P=0.121, I <sup>2</sup> =5848%	P=0.094, I <sup>2</sup> =6442%	
Redness	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Redness	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							



Table 1.34.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by peak stimulated GH concentration

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL												
Bruising	ANY	3.4% (0.9, 12.8)	0.0%	P=0.092, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA) NA	0.034 (-0.012 - 0.081)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Bruising	MILD	3.4% (0.9, 12.8)	0.0%	P=0.092, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA) NA	0.034 (-0.012 - 0.081)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Bruising	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Bruising	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.39.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years												
Pain	ANY	41.8% (30.6, 53.8)	41.7% (26.9, 58.1)	P=0.000, I <sup>2</sup> =92.6%	P=0.000, I <sup>2</sup> =93%	1.065 (0.388 - 2.925)	1.025 (0.692 - 1.517) 0.903	0.010 (-0.152 - 0.173)	P=0.179, I <sup>2</sup> =44.52%	P=0.136, I <sup>2</sup> =54.91%	P=0.142, I <sup>2</sup> =53.65%	P=0.074
Pain	HURTS LITTLE BIT	17.9% (10.5, 28.9)	11.1% (4.2, 26.1)	P=0.102, I <sup>2</sup> =61.9%	P=0.633, I <sup>2</sup> =0%	1.787 (0.527 - 6.056)	1.631 (0.572 - 4.648) 0.36	0.070 (-0.067 - 0.207)	P=0.662, I <sup>2</sup> =0%	P=0.708, I <sup>2</sup> =0%	P=0.459, I <sup>2</sup> =0%	P=0.837

Table 1.39.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years												
Pain	HURTS LITTLE MORE	7.5% (3.1, 16.7)	13.9% (5.9, 29.3)			0.495 (0.129 - 1.892)	0.548 (0.174 - 1.727) 0.304	-0.062 (-0.189 - 0.064)	P=0.458, I <sup>2</sup> =0%	P=0.505, I <sup>2</sup> =0%	P=0.165, I <sup>2</sup> =4810%	P=0.154
Pain	HURTS EVEN MORE	6.0% (2.3, 14.9)	8.3% (2.7, 22.9)			0.698 (0.132 - 3.692)	0.747 (0.194 - 2.870) 0.671	-0.021 (-0.121 - 0.079)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.401
Pain	HURTS WHOLE LOT	6.0% (2.3, 14.9)	0.0%			NA (NA - NA)	NA (NA - NA) NA	0.060 (0.003 - 0.117)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.613, I <sup>2</sup> =0%	P=0.751
Pain	HURTS WORST	4.5% (1.5, 13.0)	8.3% (2.7, 22.9)			0.513 (0.094 - 2.791)	0.552 (0.121 - 2.515) 0.443	-0.037 (-0.137 - 0.064)	P=0.396, I <sup>2</sup> =0%	P=0.420, I <sup>2</sup> =0%	P=0.148, I <sup>2</sup> =5227%	P=0.420

Table 1.39.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years												
Itching	ANY	11.9% (6.1, 22.1)	25.0% (13.6, 41.5)	P=0.020, I <sup>2</sup> =78.1%	P=0.694, I <sup>2</sup> =0%	0.408 (0.139 - 1.194)	0.486 (0.208 - 1.135) 0.095	-0.128 (-0.289 - 0.032)	P=0.187, I <sup>2</sup> =4264%	P=0.147, I <sup>2</sup> =5245%	P=0.438, I <sup>2</sup> =0%	P=0.062
Itching	ITCHES A LITTLE	9.0% (4.1, 18.5)	22.2% (11.5, 38.5)	P=0.015, I <sup>2</sup> =76.5%	P=0.927, I <sup>2</sup> =0%	0.353 (0.111 - 1.124)	0.411 (0.156 - 1.085) 0.073	-0.131 (-0.284 - 0.022)	P=0.084, I <sup>2</sup> =6650%	P=0.072, I <sup>2</sup> =6920%	P=0.244, I <sup>2</sup> =2618%	P=0.023
Itching	ITCHES EVEN MORE	1.5% (0.2, 9.8)	2.8% (0.4, 17.3)	P=0.331, I <sup>2</sup> =0%	P=0.164, I <sup>2</sup> =0%	0.536 (0.033 - 8.736)	0.536 (0.032 - 8.984) 0.665	-0.013 (-0.074 - 0.048)	P=0.344, I <sup>2</sup> =0%	P=0.350, I <sup>2</sup> =0%	P=0.299, I <sup>2</sup> =741%	P=0.626

Table 1.39.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Age < 6 years												
Itching	ITCHES WORSE	1.5% (0.2, 9.8)	0.0%	P=0.158, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA) NA	0.015 (-0.014 - 0.045)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.635
Overall number of abnormal injection-site reactions		41.8% (30.6, 53.8)	50.0% (34.2, 65.8)	P=0.000, I <sup>2</sup> =92.6%	P=0.000, I <sup>2</sup> =89%	0.664 (0.256 - 1.726)	0.851 (0.590 - 1.229) 0.39	-0.074 (-0.247 - 0.099)	P=0.533, I <sup>2</sup> =0%	P=0.922, I <sup>2</sup> =0%	P=0.552, I <sup>2</sup> =0%	P=0.045

Table 1.39.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years												
Pain	ANY	51.4% (43.1, 59.7)	38.4% (28.0, 49.9)	P=0.000, I <sup>2</sup> =96.7%	P=0.000, I <sup>2</sup> =92%	1.969 (1.017 - 3.810)	1.335 (0.991 - 1.799) 0.057	0.129 (0.006 - 0.252)	P=0.985, I <sup>2</sup> =0%	P=0.546, I <sup>2</sup> =0%	P=0.620, I <sup>2</sup> =0%	
Pain	HURTS LITTLE BIT	22.5% (16.3, 30.2)	15.1% (8.5, 25.2)	P=0.091, I <sup>2</sup> =63.1%	P=0.065, I <sup>2</sup> =64%	1.651 (0.767 - 3.557)	1.486 (0.801 - 2.757) 0.209	0.073 (-0.033 - 0.179)	P=0.485, I <sup>2</sup> =0%	P=0.442, I <sup>2</sup> =0%	P=0.757, I <sup>2</sup> =0%	

Table 1.39.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years												
Pain	HURTS LITTLE MORE	13.0% (8.4, 19.8)	8.2% (3.7, 17.1)			1.679 (0.633 - 4.450)	1.580 (0.659 - 3.790) 0.305	0.048 (-0.036 - 0.132)	P=0.198, I <sup>2</sup> =3954%	P=0.216, I <sup>2</sup> =3460%	P=0.074, I <sup>2</sup> =6876%	
Pain	HURTS EVEN MORE	2.2% (0.7, 6.5)	6.8% (2.9, 15.4)			0.299 (0.070 - 1.283)	0.316 (0.078 - 1.278) 0.106	-0.047 (-0.110 - 0.016)	P=0.245, I <sup>2</sup> =2586%	P=0.258, I <sup>2</sup> =2171%	P=0.037, I <sup>2</sup> =7711%	
Pain	HURTS WHOLE LOT	8.7% (5.0, 14.7)	4.1% (1.3, 12.0)			2.278 (0.608 - 8.540)	2.102 (0.625 - 7.072) 0.23	0.045 (-0.019 - 0.110)	P=0.809, I <sup>2</sup> =0%	P=0.832, I <sup>2</sup> =0%	P=0.214, I <sup>2</sup> =3538%	
Pain	HURTS WORST	5.1% (2.4, 10.3)	4.1% (1.3, 12.0)			1.247 (0.305 - 5.092)	1.225 (0.334 - 4.495) 0.76	0.009 (-0.048 - 0.067)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.39.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years												
Itching	ANY	26.1% (19.4, 34.0)	17.8% (10.6, 28.3)	P=0.001, I <sup>2</sup> =89.3%	P=0.022, I <sup>2</sup> =75%	1.680 (0.805 - 3.505)	1.459 (0.842 - 2.526) 0.178	0.082 (-0.028 - 0.192)	P=0.817, I <sup>2</sup> =0%	P=0.713, I <sup>2</sup> =0%	P=0.638, I <sup>2</sup> =0%	
Itching	ITCHES A LITTLE	23.2% (16.9, 31.0)	9.6% (4.6, 18.8)	P=0.002, I <sup>2</sup> =88.1%	P=0.092, I <sup>2</sup> =53%	2.992 (1.223 - 7.320)	2.407 (1.134 - 5.110) 0.022	0.135 (0.040 - 0.230)	P=0.881, I <sup>2</sup> =0%	P=0.761, I <sup>2</sup> =0%	P=0.161, I <sup>2</sup> =4902%	
Itching	ITCHES EVEN MORE	1.4% (0.4, 5.6)	5.5% (2.1, 13.7)	P=0.819, I <sup>2</sup> =0%	P=0.454, I <sup>2</sup> =0%	0.254 (0.046 - 1.417)	0.264 (0.050 - 1.409) 0.119	-0.040 (-0.096 - 0.016)	P=0.529, I <sup>2</sup> =0%	P=0.535, I <sup>2</sup> =0%	P=0.405, I <sup>2</sup> =0%	



Table 1.39.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Age ≥ 6 years												
Itching	ITCHES WORSE	1.4% (0.4, 5.6)	2.7% (0.7, 10.3)			0.513 (0.070 - 3.777)	0.525 (0.077 - 3.596) 0.512	-0.013 (-0.055 - 0.029)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Overall number of abnormal injection-site reactions		53.6% (45.3, 61.8)	41.1% (30.4, 52.7)			1.895 (0.985 - 3.645)	1.299 (0.980 - 1.723) 0.069	0.123 (-0.001 - 0.247)	P=0.766, I <sup>2</sup> =0%	P=0.712, I <sup>2</sup> =0%	P=0.543, I <sup>2</sup> =0%	
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.												

Table 1.34.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by peak stimulated GH concentration

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL												
Swelling	ANY	6.9% (2.6, 17.0)	3.3% (0.5, 20.2)	P=0.290, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	2.192 (0.227 - 21.186)	2.069 (0.247 - 17.302) 0.502	0.036 (-0.055 - 0.126)	P=0.756, I <sup>2</sup> =0%	P=0.761, I <sup>2</sup> =0%	P=0.774, I <sup>2</sup> =0%	
Swelling	MILD	6.9% (2.6, 17.0)	3.3% (0.5, 20.2)	P=0.290, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	2.192 (0.227 - 21.186)	2.069 (0.247 - 17.302) 0.502	0.036 (-0.055 - 0.126)	P=0.756, I <sup>2</sup> =0%	P=0.761, I <sup>2</sup> =0%	P=0.774, I <sup>2</sup> =0%	
Swelling	MODERATE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Swelling	SEVERE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							

Table 1.34.m Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by peak stimulated GH concentration

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL												
Other	ANY	5.2% (1.7, 14.8)	3.3% (0.5, 20.2)	P=0.550, I <sup>2</sup> =0%	P=0.233, I <sup>2</sup> =0%	1.571 (0.159 - 15.552)	1.552 (0.166 - 14.494) 0.7	0.018 (-0.068 - 0.105)	P=0.384, I <sup>2</sup> =0%	P=0.382, I <sup>2</sup> =0%	P=0.390, I <sup>2</sup> =0%	
Overall number of abnormal injection-site reactions		22.4% (13.5, 34.9)	6.7% (1.7, 23.1)	P=0.753, I <sup>2</sup> =0%	P=0.088, I <sup>2</sup> =0%	3.978 (0.836 - 18.927)	3.362 (0.807 - 14.010) 0.096	0.157 (0.017 - 0.298)	P=0.249, I <sup>2</sup> =2483 %	P=0.232, I <sup>2</sup> =2987 %	P=0.320, I <sup>2</sup> =0%	
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.												

Table 1.40.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Pain	ANY	59.4% (41.9, 74.7)	27.8% (12.1, 51.9)	P=0.006, I <sup>2</sup> =85.1%	P=0.006, I <sup>2</sup> =0%	5.960 (1.236 - 28.736)	2.044 (1.005 - 4.156) 0.048	0.297 (0.065 - 0.530)	P=0.562, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =1034%	P=0.827, I <sup>2</sup> =0%	
Pain	HURTS LITTLE BIT	25.0% (13.0, 42.6)	5.6% (0.8, 30.7)	P=0.835, I <sup>2</sup> =0%	P=0.269, I <sup>2</sup> =0%	5.582 (0.632 - 49.318)	4.376 (0.612 - 31.264) 0.141	0.192 (0.008 - 0.376)	P=0.639, I <sup>2</sup> =0%	P=0.619, I <sup>2</sup> =0%	P=0.833, I <sup>2</sup> =0%	

Table 1.40.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Pain	HURTS LITTLE MORE	15.6% (6.7, 32.5)	5.6% (0.8, 30.7)			3.137 (0.323 - 30.479)	2.687 (0.356 - 20.295) 0.338	0.096 (-0.065 - 0.257)	P=0.735, I <sup>2</sup> =0%	P=0.754, I <sup>2</sup> =0%	P=0.682, I <sup>2</sup> =0%	
Pain	HURTS EVEN MORE	6.3% (1.6, 21.8)	11.1% (2.8, 35.2)			0.471 (0.056 - 3.970)	0.526 (0.087 - 3.197) 0.486	-0.054 (-0.217 - 0.109)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Pain	HURTS WHOLE LOT	9.4% (3.1, 25.4)	0.0%			NA (NA - NA)	NA (NA - NA) NA	0.090 (-0.010 - 0.189)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Pain	HURTS WORST	3.1% (0.4, 19.1)	5.6% (0.8, 30.7)			0.500 (0.028 - 8.952)	0.526 (0.037 - 7.554) 0.637	-0.027 (-0.148 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.40.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I²)		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I²)			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Itching	ANY	15.6% (6.7, 32.5)	16.7% (5.5, 40.9)	P=0.016, I²=0%	P=0.045, I²=0%	0.833 (0.153 - 4.537)	0.877 (0.262 - 2.940) 0.832	-0.021 (-0.219 - 0.177)	P=1.000, I²=0%	P=1.000, I²=0%	P=1.000, I²=0%	
Itching	ITCHES A LITTLE	15.6% (6.7, 32.5)	5.6% (0.8, 30.7)	P=0.016, I²=0%	P=0.269, I²=0%	3.214 (0.321 - 32.206)	2.632 (0.354 - 19.559) 0.344	0.093 (-0.064 - 0.250)	P=1.000, I²=0%	P=1.000, I²=0%	P=1.000, I²=0%	
Itching	ITCHES EVEN MORE	0.0%	11.1% (2.8, 35.2)	P=1.000, I²=0%	P=0.110, I²=0%	NA (NA - NA)	NA (NA - NA) NA	-0.114 (-0.260 - 0.033)	P=1.000, I²=0%	P=1.000, I²=0%	P=1.000, I²=0%	

Table 1.40.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Female												
Itching	ITCHES WORSE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							
Overall number of abnormal injection-site reactions		59.4% (41.9, 74.7)	27.8% (12.1, 51.9)	P=0.006, I <sup>2</sup> =85.1%	P=0.006, I <sup>2</sup> =0%	5.960 (1.236 - 28.736)	2.044 (1.005 - 4.156) 0.048	0.297 (0.065 - 0.530)	P=0.562, I <sup>2</sup> =0%	P=0.291, I <sup>2</sup> =1034%	P=0.827, I <sup>2</sup> =0%	

Table 1.40.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Pain	ANY	46.2% (38.9, 53.7)	41.8% (32.1, 52.1)	P=0.000, I <sup>2</sup> =97.4%	P=0.000, I <sup>2</sup> =95%	1.309 (0.721 - 2.376)	1.118 (0.869 - 1.439) 0.387	0.049 (-0.059 - 0.157)	P=0.689, I <sup>2</sup> =0%	P=0.455, I <sup>2</sup> =0%	P=0.799, I <sup>2</sup> =0%	P=0.198
Pain	HURTS LITTLE BIT	20.2% (14.9, 26.9)	15.4% (9.3, 24.3)	P=0.012, I <sup>2</sup> =83.3%	P=0.085, I <sup>2</sup> =63%	1.423 (0.713 - 2.841)	1.324 (0.759 - 2.309) 0.323	0.050 (-0.044 - 0.143)	P=0.934, I <sup>2</sup> =0%	P=0.873, I <sup>2</sup> =0%	P=0.789, I <sup>2</sup> =0%	P=0.325



Table 1.40.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Pain	HURTS LITTLE MORE	10.4% (6.7, 15.9)	11.0% (6.0, 19.2)			0.949 (0.413 - 2.180)	0.956 (0.466 - 1.960) 0.902	-0.005 (-0.082 - 0.073)	P=0.380, I <sup>2</sup> =0%	P=0.376, I <sup>2</sup> =0%	P=0.443, I <sup>2</sup> =0%	P=0.426
Pain	HURTS EVEN MORE	2.9% (1.2, 6.8)	6.6% (3.0, 13.9)			0.417 (0.122 - 1.426)	0.444 (0.141 - 1.394) 0.164	-0.036 (-0.093 - 0.020)	P=0.373, I <sup>2</sup> =0%	P=0.393, I <sup>2</sup> =0%	P=0.025, I <sup>2</sup> =8017%	P=0.815
Pain	HURTS WHOLE LOT	7.5% (4.4, 12.5)	3.3% (1.1, 9.7)			2.478 (0.673 - 9.119)	2.306 (0.683 - 7.790) 0.178	0.043 (-0.010 - 0.096)	P=0.628, I <sup>2</sup> =0%	P=0.610, I <sup>2</sup> =0%	P=0.574, I <sup>2</sup> =0%	P=0.989
Pain	HURTS WORST	5.2% (2.7, 9.7)	5.5% (2.3, 12.5)			0.956 (0.303 - 3.020)	0.960 (0.339 - 2.719) 0.939	-0.002 (-0.058 - 0.054)	P=0.710, I <sup>2</sup> =0%	P=0.711, I <sup>2</sup> =0%	P=0.637, I <sup>2</sup> =0%	P=0.695

Table 1.40.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Itching	ANY	22.5% (16.9, 29.4)	20.9% (13.7, 30.4)	P=0.000, I <sup>2</sup> =92.6%	P=0.214, I <sup>2</sup> =33%	1.118 (0.596 - 2.100)	1.088 (0.676 - 1.751) 0.729	0.018 (-0.084 - 0.120)	P=0.190, I <sup>2</sup> =4171%	P=0.204, I <sup>2</sup> =3793%	P=0.162, I <sup>2</sup> =4883%	P=0.686
Itching	ITCHES A LITTLE	19.1% (13.9, 25.6)	15.4% (9.3, 24.3)	P=0.000, I <sup>2</sup> =91.8%	P=0.591, I <sup>2</sup> =0%	1.314 (0.660 - 2.613)	1.249 (0.709 - 2.199) 0.442	0.038 (-0.056 - 0.132)	P=0.084, I <sup>2</sup> =6658%	P=0.097, I <sup>2</sup> =6375%	P=0.049, I <sup>2</sup> =7427%	P=0.630
Itching	ITCHES EVEN MORE	1.7% (0.6, 5.2)	3.3% (1.1, 9.7)	P=0.563, I <sup>2</sup> =0%	P=0.566, I <sup>2</sup> =0%	0.518 (0.102 - 2.618)	0.525 (0.107 - 2.566) 0.426	-0.016 (-0.057 - 0.026)	P=0.429, I <sup>2</sup> =0%	P=0.430, I <sup>2</sup> =0%	P=0.432, I <sup>2</sup> =0%	P=0.536

Table 1.40.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Male												
Itching	ITCHES WORSE	1.7% (0.6, 5.2)	2.2% (0.6, 8.4)			0.795 (0.128 - 4.938)	0.802 (0.139 - 4.631) 0.805	-0.004 (-0.040 - 0.031)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.888
Overall number of abnormal injection-site reactions		48.0% (40.6, 55.4)	47.3% (37.2, 57.5)			1.060 (0.595 - 1.891)	1.024 (0.810 - 1.295) 0.843	0.011 (-0.100 - 0.123)	P=0.657, I <sup>2</sup> =0%	P=0.724, I <sup>2</sup> =0%	P=0.651, I <sup>2</sup> =0%	P=0.160
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.												

Table 1.41.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by baseline GH-stimulation strata

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL												
Pain	ANY	58.1% (45.5, 69.6)	44.1% (28.6, 60.8)	P=0.000, I <sup>2</sup> =96.1%	P=0.006, I <sup>2</sup> =83%	2.638 (0.886 - 7.858)	1.350 (0.942 - 1.935) 0.102	0.153 (-0.013 - 0.320)	P=0.112, I <sup>2</sup> =6032%	P=0.459, I <sup>2</sup> =0%	P=0.062, I <sup>2</sup> =7137%	P=0.193
Pain	HURTS LITTLE BIT	17.7% (10.1, 29.3)	23.5% (12.2, 40.5)	P=0.011, I <sup>2</sup> =75.3%	P=0.368, I <sup>2</sup> =0%	0.709 (0.248 - 2.029)	0.770 (0.351 - 1.692) 0.516	-0.054 (-0.222 - 0.114)	P=0.324, I <sup>2</sup> =0%	P=0.300, I <sup>2</sup> =676%	P=0.522, I <sup>2</sup> =0%	P=0.065

Table 1.41.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by baseline GH-stimulation strata

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL												
Pain	HURTS LITTLE MORE	17.7% (10.1, 29.3)	2.9% (0.4, 18.1)			8.142 (0.963 - 68.833)	6.212 (0.853 - 45.224) 0.071	0.151 (0.043 - 0.260)	P=0.337, I <sup>2</sup> =0%	P=0.397, I <sup>2</sup> =0%	P=0.037, I <sup>2</sup> =7707%	P=0.051
Pain	HURTS EVEN MORE	6.5% (2.4, 16.0)	8.8% (2.9, 24.0)			0.724 (0.150 - 3.504)	0.746 (0.179 - 3.120) 0.688	-0.022 (-0.134 - 0.090)	P=0.540, I <sup>2</sup> =0%	P=0.549, I <sup>2</sup> =0%	P=0.428, I <sup>2</sup> =0%	P=0.437
Pain	HURTS WHOLE LOT	12.9% (6.6, 23.7)	0.0%			NA (NA - NA)	NA (NA - NA) NA	0.132 (0.048 - 0.216)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.374
Pain	HURTS WORST	3.2% (0.8, 12.0)	8.8% (2.9, 24.0)			0.343 (0.052 - 2.241)	0.378 (0.069 - 2.086) 0.265	-0.054 (-0.157 - 0.049)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.256

Table 1.41.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by baseline GH-stimulation strata

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL												
Itching	ANY	21.0% (12.6, 32.8)	20.6% (10.1, 37.3)	P=0.003, I <sup>2</sup> =80.5%	P=0.122, I <sup>2</sup> =46%	1.063 (0.362 - 3.123)	1.045 (0.478 - 2.282) 0.912	0.009 (-0.153 - 0.171)	P=0.578, I <sup>2</sup> =0%	P=0.585, I <sup>2</sup> =0%	P=0.549, I <sup>2</sup> =0%	P=0.957
Itching	ITCHES A LITTLE	21.0% (12.6, 32.8)	14.7% (6.3, 30.8)	P=0.003, I <sup>2</sup> =80.5%	P=0.344, I <sup>2</sup> =0%	1.627 (0.513 - 5.164)	1.460 (0.584 - 3.653) 0.418	0.067 (-0.085 - 0.219)	P=0.379, I <sup>2</sup> =0%	P=0.417, I <sup>2</sup> =0%	P=0.170, I <sup>2</sup> =4698%	P=0.797
Itching	ITCHES EVEN MORE	0.0%	0.0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%							P=0.752

Table 1.41.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by baseline GH-stimulation strata

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: ≤ 5 ng/mL												
Itching	ITCHES WORSE	0.0%	5.9% (1.5, 20.7)	P=1.000, I <sup>2</sup> =0%	P=0.157, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA)	-0.058 (-0.137 - 0.021)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.199
Overall number of abnormal injection-site reactions		58.1% (45.5, 69.6)	44.1% (28.6, 60.8)	P=0.000, I <sup>2</sup> =96.1%	P=0.006, I <sup>2</sup> =83%	2.638 (0.886 - 7.858)	1.350 (0.942 - 1.935) 0.102	0.153 (-0.013 - 0.320)	P=0.112, I <sup>2</sup> =6032 %	P=0.459, I <sup>2</sup> =0%	P=0.062, I <sup>2</sup> =7137 %	P=0.127

Table 1.41.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by baseline GH-stimulation strata

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL												
Pain	ANY	44.1% (36.1, 52.3)	37.3% (27.2, 48.7)	P=0.000, I <sup>2</sup> =94.6%	P=0.000, I <sup>2</sup> =95%	1.392 (0.732 - 2.645)	1.169 (0.857 - 1.596) 0.324	0.063 (-0.058 - 0.185)	P=0.134, I <sup>2</sup> =5539%	P=0.068, I <sup>2</sup> =6994%	P=0.164, I <sup>2</sup> =4832%	
Pain	HURTS LITTLE BIT	22.4% (16.3, 29.9)	9.3% (4.5, 18.3)	P=0.128, I <sup>2</sup> =56.1%	P=0.164, I <sup>2</sup> =43%	2.843 (1.178 - 6.866)	2.384 (1.113 - 5.106) 0.025	0.130 (0.036 - 0.223)	P=0.575, I <sup>2</sup> =0%	P=0.504, I <sup>2</sup> =0%	P=0.887, I <sup>2</sup> =0%	



Table 1.41.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by baseline GH-stimulation strata

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL												
Pain	HURTS LITTLE MORE	8.4% (4.8, 14.2)	13.3% (7.3, 23.0)			0.579 (0.234 - 1.434)	0.624 (0.286 - 1.359) 0.235	-0.050 (-0.138 - 0.038)	P=0.865, I <sup>2</sup> =0%	P=0.813, I <sup>2</sup> =0%	P=0.696, I <sup>2</sup> =0%	
Pain	HURTS EVEN MORE	2.1% (0.7, 6.3)	6.7% (2.8, 15.0)			0.277 (0.062 - 1.235)	0.309 (0.078 - 1.218) 0.093	-0.046 (-0.107 - 0.014)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Pain	HURTS WHOLE LOT	5.6% (2.8, 10.8)	4.0% (1.3, 11.7)			1.415 (0.360 - 5.558)	1.385 (0.384 - 4.998) 0.619	0.015 (-0.042 - 0.073)	P=0.343, I <sup>2</sup> =0%	P=0.339, I <sup>2</sup> =0%	P=0.430, I <sup>2</sup> =0%	
Pain	HURTS WORST	5.6% (2.8, 10.8)	4.0% (1.3, 11.7)			1.420 (0.355 - 5.678)	1.377 (0.387 - 4.901) 0.622	0.015 (-0.042 - 0.072)	P=0.825, I <sup>2</sup> =0%	P=0.818, I <sup>2</sup> =0%	P=0.743, I <sup>2</sup> =0%	

Table 1.41.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by baseline GH-stimulation strata

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL												
Itching	ANY	21.7% (15.7, 29.2)	20.0% (12.4, 30.6)			1.100 (0.544 - 2.226)	1.075 (0.627 - 1.845) 0.792	0.015 (-0.096 - 0.126)	P=0.293 , I <sup>2</sup> =954 %	P=0.308 , I <sup>2</sup> =382 %	P=0.261 , I <sup>2</sup> =2087 %	
Itching	ITCHES A LITTLE	17.5% (12.1, 24.6)	13.3% (7.3, 23.0)			1.368 (0.618 - 3.030)	1.302 (0.661 - 2.563) 0.445	0.040 (-0.058 - 0.139)	P=0.112 , I <sup>2</sup> =6033 %	P=0.127 , I <sup>2</sup> =5703 %	P=0.066 , I <sup>2</sup> =7052 %	
Itching	ITCHES EVEN MORE	2.1% (0.7, 6.3)	6.7% (2.8, 15.0)			0.303 (0.071 - 1.285)	0.314 (0.077 - 1.278) 0.106	-0.046 (-0.107 - 0.016)	P=0.186 , I <sup>2</sup> =4276 %	P=0.195 , I <sup>2</sup> =4056 %	P=0.069 , I <sup>2</sup> =6965 %	

Table 1.41.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by baseline GH-stimulation strata

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Baseline GH-stimulation strata: > 5 ng/mL												
Itching	ITCHES WORSE	2.1% (0.7, 6.3)	0.0%	P=0.033, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA) NA	0.021 (-0.003 - 0.044)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Overall number of abnormal injection-site reactions		46.2% (38.2, 54.4)	44.0% (33.2, 55.3)	P=0.000, I <sup>2</sup> =94.9%	P=0.000, I <sup>2</sup> =93%	1.092 (0.588 - 2.029)	1.041 (0.785 - 1.380) 0.782	0.018 (-0.108 - 0.144)	P=0.530, I <sup>2</sup> =0%	P=0.462, I <sup>2</sup> =0%	P=0.537, I <sup>2</sup> =0%	
Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology. meta-analysis for interaction was performed based on RRs from different subgroups.												

Table 1.42.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

						Lonapegsomatropin vs. Daily somatropin						
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Pain	ANY	46.2% (37.2, 55.4)	45.3% (32.1, 59.2)	P=0.000, I <sup>2</sup> =97.1%	P=0.000, I <sup>2</sup> =96%	1.147 (0.597 - 2.205)	1.053 (0.821 - 1.351) 0.683	0.023 (-0.086 - 0.132)	P=0.247, I <sup>2</sup> =2543%	P=0.165, I <sup>2</sup> =4823%	P=0.244, I <sup>2</sup> =2647%	P=0.075
Pain	HURTS LITTLE BIT	21.4% (15.4, 28.8)	17.2% (10.2, 27.6)	P=0.044, I <sup>2</sup> =75.3%	P=0.056, I <sup>2</sup> =73%	1.415 (0.686 - 2.920)	1.316 (0.737 - 2.350) 0.353	0.049 (-0.050 - 0.148)	P=0.594, I <sup>2</sup> =0%	P=0.544, I <sup>2</sup> =0%	P=0.814, I <sup>2</sup> =0%	P=0.438

Table 1.42.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Pain	HURTS LITTLE MORE	13.6% (8.5, 20.8)	11.8% (6.2, 21.1)			1.046 (0.437 - 2.500)	1.039 (0.491 - 2.199) 0.92	0.004 (-0.077 - 0.086)	P=0.603, I <sup>2</sup> =0%	P=0.607, I <sup>2</sup> =0%	P=0.572, I <sup>2</sup> =0%	P=0.896
Pain	HURTS EVEN MORE	4.5% (1.8, 10.9)	15.4% (7.6, 28.6)			0.268 (0.073 - 0.986)	0.311 (0.097 - 0.993) 0.049	-0.058 (-0.121 - 0.005)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.462
Pain	HURTS WHOLE LOT	9.6% (5.4, 16.6)	6.0% (2.1, 15.9)			2.158 (0.568 - 8.199)	2.005 (0.590 - 6.806) 0.265	0.036 (-0.020 - 0.092)	P=0.711, I <sup>2</sup> =0%	P=0.691, I <sup>2</sup> =0%	P=0.451, I <sup>2</sup> =0%	P=0.824
Pain	HURTS WORST	5.4% (2.4, 11.5)	8.3% (3.3, 19.2)			0.805 (0.215 - 3.013)	0.820 (0.245 - 2.747) 0.747	-0.009 (-0.063 - 0.046)	P=0.583, I <sup>2</sup> =0%	P=0.589, I <sup>2</sup> =0%	P=0.372, I <sup>2</sup> =0%	P=0.780

Table 1.42.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Itching	ANY	24.5% (17.6, 33.0)	22.4% (14.5, 32.9)	P=0.000, I <sup>2</sup> =93%	P=0.105, I <sup>2</sup> =62%	0.930 (0.474 - 1.828)	0.948 (0.574 - 1.564) 0.834	-0.011 (-0.117 - 0.094)	P=0.213, I <sup>2</sup> =3554%	P=0.205, I <sup>2</sup> =3786%	P=0.258, I <sup>2</sup> =2200%	P=0.287
Itching	ITCHES A LITTLE	21.6% (15.1, 29.9)	14.4% (8.3, 23.6)	P=0.000, I <sup>2</sup> =91.9%	P=0.654, I <sup>2</sup> =0%	1.297 (0.616 - 2.729)	1.240 (0.665 - 2.312) 0.498	0.034 (-0.061 - 0.130)	P=0.066, I <sup>2</sup> =7041%	P=0.078, I <sup>2</sup> =6789%	P=0.036, I <sup>2</sup> =7719%	P=0.553
Itching	ITCHES EVEN MORE	1.3% (0.3, 5.2)	7.7% (3.2, 17.4)	P=0.887, I <sup>2</sup> =0%	P=0.132, I <sup>2</sup> =56%	0.210 (0.040 - 1.099)	0.221 (0.044 - 1.107) 0.066	-0.047 (-0.100 - 0.007)	P=0.405, I <sup>2</sup> =0%	P=0.422, I <sup>2</sup> =0%	P=0.076, I <sup>2</sup> =6834%	P=0.387

Table 1.42.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I²)		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I²)			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Isolated idiopathic												
Itching	ITCHES WORSE	2.1% (0.6, 7.1)	2.0% (0.4, 9.2)	P=0.308, I²=3.9%	P=0.578, I²=0%	1.091 (0.096 - 12.448)	1.088 (0.102 - 11.604) 0.944	0.001 (-0.028 - 0.030)	P=1.000, I²=0%	P=1.000, I²=0%	P=1.000, I²=0%	P=0.638
Overall number of abnormal injection-site reactions		47.0% (37.9, 56.2)	46.9% (34.4, 59.9)	P=0.000, I²=97.1%	P=0.000, I²=96%	0.877 (0.465 - 1.655)	0.953 (0.755 - 1.202) 0.683	-0.023 (-0.135 - 0.089)	P=0.551, I²=0%	P=0.714, I²=0%	P=0.551, I²=0%	P=0.048

Table 1.42.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Pain	ANY	47.5% (29.9, 65.8)	18.0% (5.2, 46.7)	P=0.023, I <sup>2</sup> =80.8%	P=0.496, I <sup>2</sup> =0%	7.579 (1.220 - 47.084)	3.424 (0.932 - 12.574) 0.064	0.336 (0.107 - 0.565)	P=0.569, I <sup>2</sup> =0%	P=0.749, I <sup>2</sup> =0%	P=0.210, I <sup>2</sup> =3646%	
Pain	HURTS LITTLE BIT	25.5% (13.2, 43.5)	10.1% (2.0, 37.8)	P=0.263, I <sup>2</sup> =20.3%	P=0.861, I <sup>2</sup> =0%	4.826 (0.505 - 46.124)	3.618 (0.499 - 26.206) 0.203	0.181 (-0.013 - 0.376)	P=0.594, I <sup>2</sup> =0%	P=0.639, I <sup>2</sup> =0%	P=0.497, I <sup>2</sup> =0%	



Table 1.42.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Pain	HURTS LITTLE MORE	4.5% (0.9, 19.6)	6.4% (0.9, 34.4)			NA (NA - NA)	NA (NA - NA) NA	0.033 (-0.028 - 0.094)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Pain	HURTS EVEN MORE	4.5% (0.9, 19.6)	6.4% (0.9, 34.4)									
Pain	HURTS WHOLE LOT	6.1% (1.5, 21.4)	6.4% (0.9, 34.4)			NA (NA - NA)	NA (NA - NA) NA	0.060 (-0.022 - 0.141)	P=NA, I <sup>2</sup> =NA%	P=NA, I <sup>2</sup> =NA%	P=0.620, I <sup>2</sup> =0%	
Pain	HURTS WORST	12.5% (4.4, 30.7)	10.1% (2.0, 37.8)			1.500 (0.134 - 16.819)	1.421 (0.171 - 11.835) 0.745	0.029 (-0.134 - 0.192)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.42.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Itching	ANY	29.1% (15.0, 48.9)	10.1% (2.0, 37.8)	P=0.076, I <sup>2</sup> =68.3%	P=0.861, I <sup>2</sup> =0%	5.281 (0.544 - 51.237)	3.704 (0.527 - 26.043) 0.188	0.187 (-0.004 - 0.379)	P=0.388, I <sup>2</sup> =0%	P=0.465, I <sup>2</sup> =0%	P=0.184, I <sup>2</sup> =4338%	
Itching	ITCHES A LITTLE	26.0% (12.3, 46.7)	6.4% (0.9, 34.4)	P=0.088, I <sup>2</sup> =65.6%	P=0.792, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA) NA	0.197 (0.062 - 0.332)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Itching	ITCHES EVEN MORE	5.0% (1.0, 21.5)	6.4% (0.9, 34.4)	P=0.535, I <sup>2</sup> =0%	P=0.792, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA) NA	0.027 (-0.029 - 0.082)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.42.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Isolated organic												
Itching	ITCHES WORSE	4.5% (0.9, 19.6)	10.1% (2.0, 37.8)			0.444 (0.025 - 8.031)	0.474 (0.033 - 6.744) 0.581	-0.036 (-0.181 - 0.108)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Overall number of abnormal injection-site reactions		50.4% (32.0, 68.7)	18.0% (5.2, 46.7)			9.425 (1.463 - 60.713)	3.661 (1.007 - 13.310) 0.049	0.369 (0.143 - 0.595)	P=0.492, I <sup>2</sup> =0%	P=0.743, I <sup>2</sup> =0%	P=0.136, I <sup>2</sup> =5506%	

Table 1.42.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Pain	ANY	71.3% (47.5, 87.2)	46.4% (21.4, 73.4)			3.850 (0.742 - 19.964)	1.633 (0.825 - 3.234) 0.159	0.284 (-0.049 - 0.616)	P=0.682, I <sup>2</sup> =0%	P=0.876, I <sup>2</sup> =0%	P=0.684, I <sup>2</sup> =0%	
Pain	HURTS LITTLE BIT	20.8% (8.5, 42.6)	13.3% (2.6, 46.5)			2.571 (0.246 - 26.851)	2.222 (0.286 - 17.269) 0.445	0.109 (-0.129 - 0.348)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.42.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Pain	HURTS LITTLE MORE	25.7% (11.5, 47.8)	20.9% (6.1, 51.6)			1.538 (0.239 - 9.896)	1.389 (0.327 - 5.898) 0.656	0.070 (-0.219 - 0.358)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Pain	HURTS EVEN MORE	12.5% (3.0, 40.0)	13.3% (2.6, 46.5)			0.941 (0.074 - 12.002)	0.944 (0.081 - 10.969) 0.964	-0.005 (-0.215 - 0.205)	P=0.607, I <sup>2</sup> =0%	P=0.607, I <sup>2</sup> =0%	P=0.623, I <sup>2</sup> =0%	
Pain	HURTS WHOLE LOT	16.0% (5.7, 37.4)	10.1% (1.3, 48.4)			NA (NA - NA)	NA (NA - NA) NA	0.149 (-0.004 - 0.302)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Pain	HURTS WORST	7.2% (1.4, 29.2)	13.3% (2.6, 46.5)			0.529 (0.030 - 9.499)	0.556 (0.039 - 7.957) 0.665	-0.040 (-0.232 - 0.153)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.42.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Itching	ANY	24.0% (10.3, 46.4)	29.2% (10.6, 58.9)			0.833 (0.158 - 4.399)	0.870 (0.244 - 3.109) 0.831	-0.035 (-0.357 - 0.287)	P=0.638, I <sup>2</sup> =0%	P=0.643, I <sup>2</sup> =0%	P=0.633, I <sup>2</sup> =0%	
Itching	ITCHES A LITTLE	24.0% (10.3, 46.4)	29.2% (10.6, 58.9)			0.833 (0.158 - 4.399)	0.870 (0.244 - 3.109) 0.831	-0.035 (-0.357 - 0.287)	P=0.638, I <sup>2</sup> =0%	P=0.643, I <sup>2</sup> =0%	P=0.633, I <sup>2</sup> =0%	
Itching	ITCHES EVEN MORE	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)									
Itching	ITCHES WORSE	5.6% (0.8, 31.3)	10.1% (1.3, 48.4)									

Table 1.42.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by etiology and extend of GHD

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Multiple pituitary hormone deficiencies												
Overall number of abnormal injection-site reactions		71.3% (47.5, 87.2)	46.4% (21.4, 73.4)	P=0.149, I <sup>2</sup> =51.9%	P=0.530, I <sup>2</sup> =0%	3.850 (0.742 - 19.964)	1.633 (0.825 - 3.234) 0.159	0.284 (-0.049 - 0.616)	P=0.682, I <sup>2</sup> =0%	P=0.876, I <sup>2</sup> =0%	P=0.684, I <sup>2</sup> =0%	
<p>Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology.                      meta-analysis for interaction was performed based on RRs from different subgroups.                      Due to convergent issue, inverse variance method was used for pooling studies than generalized linear mixed model (GLMM). This may cause different estimate than using GLMM.</p>												

Table 1.43.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by peak stimulated GH concentration

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL												
Pain	ANY	51.0% (41.9, 60.0)	45.9% (33.8, 58.5)	P=0.000, I <sup>2</sup> =96.6%	P=0.000, I <sup>2</sup> =94%	1.522 (0.812 - 2.850)	1.188 (0.911 - 1.549) 0.204	0.081 (-0.039 - 0.200)	P=0.868, I <sup>2</sup> =0%	P=0.494, I <sup>2</sup> =0%	P=0.966, I <sup>2</sup> =0%	P=0.883
Pain	HURTS LITTLE BIT	23.3% (17.1, 30.9)	15.8% (9.2, 25.8)	P=0.344, I <sup>2</sup> =0%	P=0.273, I <sup>2</sup> =17%	1.690 (0.816 - 3.501)	1.524 (0.840 - 2.766) 0.166	0.080 (-0.024 - 0.183)	P=0.650, I <sup>2</sup> =0%	P=0.610, I <sup>2</sup> =0%	P=0.817, I <sup>2</sup> =0%	P=0.933



Table 1.43.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by peak stimulated GH concentration

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL												
Pain	HURTS LITTLE MORE	14.0% (8.8, 21.5)	13.4% (7.4, 23.3)	P=0.013, I <sup>2</sup> =83.7%	P=0.231, I <sup>2</sup> =30%	0.902 (0.386 - 2.104)	0.916 (0.446 - 1.881) 0.81	-0.011 (-0.099 - 0.078)	P=0.442, I <sup>2</sup> =0%	P=0.434, I <sup>2</sup> =0%	P=0.538, I <sup>2</sup> =0%	P=0.353
Pain	HURTS EVEN MORE	4.0% (1.7, 9.3)	14.2% (7.1, 26.6)	P=0.230, I <sup>2</sup> =30.7%	P=0.062, I <sup>2</sup> =71%	0.351 (0.106 - 1.162)	0.385 (0.129 - 1.153) 0.088	-0.054 (-0.123 - 0.014)	P=0.309, I <sup>2</sup> =341%	P=0.335, I <sup>2</sup> =0%	P=0.007, I <sup>2</sup> =8649%	P=0.470
Pain	HURTS WHOLE LOT	13.0% (7.6, 21.2)	2.0% (0.4, 9.2)	P=0.015, I <sup>2</sup> =83.2%	P=0.708, I <sup>2</sup> =0%	8.137 (1.022 - 64.815)	7.010 (0.948 - 51.861) 0.056	0.076 (0.024 - 0.127)	P=0.328, I <sup>2</sup> =0%	P=0.365, I <sup>2</sup> =0%	P=0.003, I <sup>2</sup> =8891%	P=0.126
Pain	HURTS WORST	6.5% (3.0, 13.4)	7.7% (3.1, 18.1)	P=0.091, I <sup>2</sup> =65.1%	P=0.163, I <sup>2</sup> =49%	0.793 (0.210 - 2.987)	0.809 (0.242 - 2.705) 0.731	-0.010 (-0.066 - 0.047)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.873

Table 1.43.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by peak stimulated GH concentration

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL												
Itching	ANY	22.9% (16.5, 30.9)	21.2% (13.4, 31.9)	P=0.006, I <sup>2</sup> =86.5%	P=0.138, I <sup>2</sup> =55%	1.057 (0.530 - 2.108)	1.043 (0.616 - 1.767) 0.876	0.009 (-0.100 - 0.117)	P=0.644, I <sup>2</sup> =0%	P=0.655, I <sup>2</sup> =0%	P=0.611, I <sup>2</sup> =0%	P=0.797
Itching	ITCHES A LITTLE	20.0% (14.0, 27.7)	14.3% (8.1, 24.0)	P=0.013, I <sup>2</sup> =83.8%	P=0.405, I <sup>2</sup> =0%	1.403 (0.651 - 3.025)	1.321 (0.697 - 2.504) 0.393	0.045 (-0.053 - 0.142)	P=0.449, I <sup>2</sup> =0%	P=0.484, I <sup>2</sup> =0%	P=0.297, I <sup>2</sup> =798%	P=0.791
Itching	ITCHES EVEN MORE	1.4% (0.3, 5.3)	4.0% (1.3, 11.6)	P=0.961, I <sup>2</sup> =0%	P=0.607, I <sup>2</sup> =0%	0.350 (0.057 - 2.137)	0.358 (0.061 - 2.102) 0.256	-0.024 (-0.070 - 0.022)	P=0.708, I <sup>2</sup> =0%	P=0.711, I <sup>2</sup> =0%	P=0.606, I <sup>2</sup> =0%	P=0.967

Table 1.43.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by peak stimulated GH concentration

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: < 8 ng/mL												
Itching	ITCHES WORSE	2.0% (0.6, 6.7)	3.7% (1.1, 12.1)	P=0.395, I <sup>2</sup> =0%	P=0.390, I <sup>2</sup> =0%	0.527 (0.071 - 3.886)	0.539 (0.079 - 3.690) 0.529	-0.012 (-0.051 - 0.027)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=0.670
Overall number of abnormal injection-site reactions		51.5% (42.5, 60.4)	48.1% (36.1, 60.3)	P=0.000, I <sup>2</sup> =96.4%	P=0.000, I <sup>2</sup> =93%	1.283 (0.694 - 2.372)	1.106 (0.859 - 1.424) 0.436	0.050 (-0.072 - 0.171)	P=0.964, I <sup>2</sup> =0%	P=0.775, I <sup>2</sup> =0%	P=0.942, I <sup>2</sup> =0%	P=0.607

Table 1.43.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by peak stimulated GH concentration

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL												
Pain	ANY	46.5% (31.6, 62.0)	48.8% (26.5, 71.5)	P=0.000, I <sup>2</sup> =93.5%	P=0.012, I <sup>2</sup> =84%	2.222 (0.670 - 7.375)	1.379 (0.826 - 2.304) 0.219	0.114 (-0.050 - 0.278)	P=0.395, I <sup>2</sup> =0%	P=0.257, I <sup>2</sup> =2222%	P=0.865, I <sup>2</sup> =0%	
Pain	HURTS LITTLE BIT	26.1% (14.2, 43.0)	15.1% (5.3, 36.0)	P=0.027, I <sup>2</sup> =79.6%	P=0.194, I <sup>2</sup> =41%	1.800 (0.406 - 7.985)	1.552 (0.492 - 4.893) 0.453	0.055 (-0.076 - 0.186)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	

Table 1.43.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by peak stimulated GH concentration

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ€™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL												
Pain	HURTS LITTLE MORE	13.0% (5.9, 26.2)	5.2% (1.0, 22.0)			3.542 (0.388 - 32.332)	3.103 (0.404 - 23.846) 0.276	0.070 (-0.029 - 0.169)	P=0.620, I <sup>2</sup> =0%	P=0.654, I <sup>2</sup> =0%	P=0.343, I <sup>2</sup> =0%	
Pain	HURTS EVEN MORE	5.2% (1.5, 16.3)	5.2% (1.0, 22.0)			1.037 (0.086 - 12.455)	1.034 (0.102 - 10.507) 0.977	0.001 (-0.077 - 0.079)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Pain	HURTS WHOLE LOT	5.5% (1.8, 15.6)	9.9% (2.8, 29.0)			0.768 (0.124 - 4.762)	0.776 (0.134 - 4.477) 0.777	-0.015 (-0.122 - 0.092)	P=0.211, I <sup>2</sup> =3604%	P=0.217, I <sup>2</sup> =3440%	P=0.179, I <sup>2</sup> =4468%	
Pain	HURTS WORST	7.8% (2.9, 19.1)	9.9% (2.8, 29.0)			1.038 (0.173 - 6.224)	1.034 (0.207 - 5.171) 0.967	0.002 (-0.106 - 0.111)	P=0.667, I <sup>2</sup> =0%	P=0.665, I <sup>2</sup> =0%	P=0.678, I <sup>2</sup> =0%	

Table 1.43.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by peak stimulated GH concentration

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin n	Daily somatropin n	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL												
Itching	ANY	33.0% (19.8, 49.6)	20.9% (9.6, 39.6)	P=0.006, I <sup>2</sup> =86.8%	P=0.369, I <sup>2</sup> =0%	1.169 (0.379 - 3.610)	1.121 (0.489 - 2.567) 0.788	0.024 (-0.148 - 0.196)	P=0.142, I <sup>2</sup> =5355%	P=0.158, I <sup>2</sup> =4983%	P=0.120, I <sup>2</sup> =5860%	
Itching	ITCHES A LITTLE	32.4% (18.9, 49.8)	13.3% (5.1, 30.6)	P=0.015, I <sup>2</sup> =83%	P=1.000, I <sup>2</sup> =0%	1.521 (0.445 - 5.198)	1.422 (0.495 - 4.090) 0.513	0.056 (-0.102 - 0.214)	P=0.035, I <sup>2</sup> =7739%	P=0.048, I <sup>2</sup> =7431%	P=0.010, I <sup>2</sup> =8494%	
Itching	ITCHES EVEN MORE	2.7% (0.5, 12.3)	9.9% (2.8, 29.0)	P=0.671, I <sup>2</sup> =0%	P=0.336, I <sup>2</sup> =0%	0.259 (0.024 - 2.796)	0.259 (0.023 - 2.852) 0.269	-0.049 (-0.146 - 0.047)	P=0.198, I <sup>2</sup> =3964%	P=0.201, I <sup>2</sup> =3874%	P=0.133, I <sup>2</sup> =5580%	

Table 1.43.m Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by peak stimulated GH concentration

		Lonapegsomatropin vs. Daily somatropin										
		Meta Analysis		Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )		Meta Analysis			Heterogeneity Test (KH-PMβ <sup>€</sup> ™s Q, I <sup>2</sup> )			
Symptom	Severity	Lonapeg somatropin Mean (95%CI)	Daily somatropin Mean (95%CI)	Lonapeg somatropin	Daily somatropin	OR [95% CI]	RR [95% CI] p value	RD [95% CI]	OR	RR	RD	Interaction
Peak stimulated GH concentration at baseline: ≥ 8 ng/mL												
Itching	ITCHES WORSE	2.7% (0.5, 12.3)	3.1% (0.4, 19.1)	P=0.671, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	NA (NA - NA)	NA (NA - NA) NA	0.017 (-0.016 - 0.051)	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	P=1.000, I <sup>2</sup> =0%	
Overall number of abnormal injection-site reactions		49.3% (33.4, 65.4)	41.7% (23.4, 62.6)	P=0.000, I <sup>2</sup> =94.6%	P=0.014, I <sup>2</sup> =84%	1.628 (0.549 - 4.827)	1.223 (0.767 - 1.948) 0.398	0.082 (-0.097 - 0.261)	P=0.544, I <sup>2</sup> =0%	P=0.801, I <sup>2</sup> =0%	P=0.381, I <sup>2</sup> =0%	
<p>Meta-analysis was performed using a fixed effect model. KH-PM: Knapp-Hartung method with Paule-Mandel-methodology.                      meta-analysis for interaction was performed based on RRs from different subgroups.                      Due to convergent issue, inverse variance method was used for pooling studies than generalized linear mixed model (GLMM). This may cause different estimate than using GLMM.</p>												